Title page

TITLE: Oral health related quality of life and clinical outcomes in patients undergoing canine disimpaction- A Randomized Control Trial.

NCT number: NCT01917604

PROPOSED DEPARTMENT & PLACE OF STUDY:

Dept. of Orthodontics, Faculty of Dentistry, Jamia Millia Islamia, New Delhi

RESEARCH PROPOSAL

TITLE: Oral health related quality of life and clinical outcomes in patients undergoing canine disimpaction- A Randomized Control Trial.
NCT number: NCT01917604

OBJECTIVES:

1. To assess oral health related quality of life in patients undergoing canine disimpaction through Questionnaire.
2. To assess periodontal outcomes between the open and closed surgical techniques.
3. To assess whether there are differences in patient reported outcomes between the open and closed surgical techniques.

1. BACKGROUND KNOWLEDGE:

Impacted canines are permanent teeth that could not erupt at its normal chronological age due to its displacement to abnormal position in the roof of mouth (palate), or due to obstruction in its path of eruption or inherent deficient eruption potential. This is a frequently occurring anomaly, present in 2% to 3% of the population.[1] Management of this problem is both time consuming and expensive and involves surgical exposure (uncovering of palatal mucosa) along with fixed orthodontic appliance to bring the canine into its normal position and alignment within the dental arch.

Two techniques for surgical exposure of palatally impacted canines are routinely followed:

a) **Open surgical technique,** involves surgical uncovering of the palatal mucosa overlying impacted canine by creation of a window in the palatal mucosa, and a dressing is placed to cover the exposed area. Then approximately 10 days later, this pack is removed and the canine is allowed to erupt naturally. Once the tooth has erupted sufficiently for an orthodontic attachment to be bonded to its surface, orthodontic treatment is commenced to bring this tooth into its correct position in dental arch the through the palatal mucosa.

b) **Closed surgical technique** involves surgical uncovering of palatal mucosa above the impacted canine by full thickness flap and bonding an attachment over the exposed

surface of canine, repositioning/suturing of palatal mucosa and then with the help of bonded attachment, orthodontically moving this canine into its correct position from beneath the palatal mucosa.[2]

2. REASON OF THE STUDY:

Through this prospective study, clinical outcomes and patient experiences for both these techniques will be evaluated.

Permanent maxillary canines usually erupt in the mouth at the age of 11 to 12 years. They play a vital role in facial appearance, dental aesthetics, arch development and functional occlusion i.e the canine guided occlusion. The process of eruption of the permanent canines leading to their final positioning in the oral cavity is complex and the longest of all the permanent teeth which may leads to impaction or eruption of these canines into abnormal position. Impacted canines are usually asymptomatic, however, impaction may cause severe complications such as development of malocclusion and some pathological conditions e.g. dentigerous cysts. The most common irreversible and adverse effect of maxillary canine impaction is root resorptions. Their impaction can also cause damage to the roots of neighboring teeth by causing resorption of their roots and the damage may be so severe that these teeth are subsequently lost. The tissue that is the dental follicle around these impacted canine teeth may undergo cystic changes. Impaction of these teeth can also lead to aesthetic problems due to a gap created in the dental arch in the area at their position. Hence negative physical and psychological impact can occur to the patient. Therefore it is important to disimpact these teeth and bring them into their correct occlusal position within the dental arch. [3,4]

There are only a few clinical trials, where open and closed surgical exposure of canine are compared on various outcomes. Most of these studies are retrospective and due to the biases involved, they provide very little conclusive evidence.[5,6,7]

A study by Wisth[5] compared closed and open techniques. 34 participants received an open exposure and 22 patients received a closed exposure. It was found that the mean duration of treatment was 4 months longer in the closed group and it was reported that this was likely due to lack of direct vision of the canine from when it was exposed to when it was brought into the line of the arch. The closed group appeared to have less periodontal damage in terms of loss or attachment and bone levels. The study however was retrospective, pretreatment equivalence was not established (in terms of participant's

age or severity of canine displacement) and therefore the risk of selection and detection bias was high.

Woloshyn[6] study, all palatally displaced canines received a closed exposure. This study found that the roots of the impacted canine and adjacent lateral incisor were slightly shorter than those of the contralateral canine and that the treated canine could be visually differentiated from the control canine in 70% to 80% of cases. They came to a conclusion that the overall consequences to the impacted canine with open technique seem better than with a closed technique. This is in contrast to findings of Becker[8] reported excellent periodontal health following alignment of canines using a closed technique. Importantly, all these mentioned studies, are retrospective and findings therefore score low in terms of evidence.

Sampaziotis et al[9] in their systematic review concluded that there is a need for randomized clinical trials (RCTs) to compare the two treatment alternatives and more RCTs should be performed in the future for stronger evidence and clarification of some controversial issues.

According to a recent Cochrane review[10], the studies conducted had high risk of bias and thus were very low in evidence to support any decision. Thus, particular conclusion as to which technique of surgical exposure is superior in terms of periodontal health, aesthetic and patient comfort cannot be attained.

The present study has been designed keeping the lacunae in previous literature in mind. Currently, there is little evidence to support one surgical technique over the other in terms of dental health, aesthetics and patient factors. Therefore, a high quality prospective clinical trial with participants randomly allocated into the two treatment groups need to be conducted. Otherwise, methods of exposing canines will be left to the personal choice of the surgeon and orthodontist.

3. METHODOLOGY:

Study design: A unicentric, randomized controlled clinical trial involving 2 parallel groups (Group 1 for open surgical technique and group 2 for closed surgical technique) where contralateral side fully erupted and normally positioned canine will be considered as control. The study will be conducted in Department of Orthodontics, Faculty of

Dentistry, Jamia Millia Islamia post ethical committee approval by institutional ethics committee.

Written informed consent will be taken from all the patients enrolling in the study.

Estimation of Sample Size: Assuming the mean difference of the primary outcome (measure of clinical attachment) as 0.5 mm with standard deviation as 0.61 mm between the open and closed exposure group (Reference : Periodontal health of palatally displaced canines treated with open or closed surgical technique: A multicenter, randomized controlled trial. American Journal of Orthodontics and Dentofacial Orthopedics August 2013 ; 176-84; Vol 144 ;Issue 2) with alpha (level of significance) <0.05 , Power=80% , 2 sided hypothesis, the total minimum sample size 40 will be required to detect the minimum significant difference of the primary outcome. The total sample size can be randomized in equal no. as 20 in each group (open and closed group). Twenty patients who meet the below mentioned criteria will be randomly allocated in each group. Participants for the trial will be identified from treatment waiting lists and new patient clinics.

Inclusion criteria:

- Patients with unilateral and favorably placed palatally ectopic maxillary canines who require surgical exposure for orthodontic alignment of impacted canine on contralateral side of same arch. The other side will be taken as control canine.
- Age 13-25 years
- Minimal orthodontic malocclusion other than the ectopic canine
- Good oral hygiene and motivation to wear fixed appliances for at least 2 years

Exclusion criteria:

- Patients with contralateral ectopic maxillary canines.
- Periodontal disease (bleeding on probing, pocket probing depths 3 mm and decreased bone levels as diagnosed from baseline panoramic imaging)
- Cases in which the canine is to be brought into the position of the lateral incisor or premolar.
- Compromising medical conditions (patients requiring antibiotic prophylaxis to prevent infective endocarditis)

Radiographic diagnosis of palatal impaction:

The horizontal parallax method will be used since it is more reliable than vertical parallax. A periapical film would be placed in mouth on the palatal aspect of the area where the tooth is normally situated. The X-ray tube is directed at right angles to a tangent to the line of the arch at this point and at appropriate angle to the horizontal plane as for any periapical view. A second film is placed in the mouth in the identical position but, on this occasion, the x-ray tube would be shifted distally but held at the same angle to the horizontal plane and directed mesially. To do this the tube should describe 30-45^0 of an arc of a circle, whose center is somewhere in the middle of the palate. The IOPA Xray which would be taken from distal will be marked "D" for identification.

Randomization:

Randomization procedures and reporting include the following steps.

1. Generation of the random allocation sequence, including details of any restrictions:

Minimization, a form of restricted randomization, is considered to be a dynamic method, since the randomization list is not produced before the trial starts, but during participant recruitment. Additionally, minimization, in contrast to the previous methods, is considered to be an adaptive randomization technique, since future participant allocation depends on previous assignments**.** Once consent had been obtained, each participant will be randomly allocated to group 1 or group 2.

2. Allocation concealment and implementation of the random allocation sequence:

Blinding of the investigator is not possible so to reduce bias one of the staff assistant who was neutral towards treatment will be allocated the job of assigning patient in the two treatment groups. The first 5 patients will be allocated according to simple randomization and from 6th patient onwards minimization will be followed.

The prognostic factors or predictors will be used like severity of impaction, age, oral hygiene, presence of crowding, and rotation of canine. The severity of the canine impaction will be assessed by a single blinded assessor, from the pretreatment panoramic imaging film, using the criteria described by Ericson and Kurol.

Treatment Protocol:

The orthodontic treatment will be done by single orthodontist who will follow a strict protocol as follows:

1. Initial orthodontic alignment will be aimed at creating space in the maxillary arch with fixed appliance therapy (0.022 slot) .The surgical procedure will be done after reaching a full size wire of 19X25 S.S with open coil spring to maintain space for the permanent canine. Anchorage preparation will also be done with the help of TPA.

2. Surgical exposure and orthodontic traction.

The tooth will be sufficiently exposed to bond an orthodontic attachment (button). NiTi closed coil (0.018"S.S. wire) spring will be used to vertically extrude highly placed palatal canine impactions till the time it erupts sufficiently so as not to resorb the roots. After that traction force will be applied followed by ligature with e chain which will be hooked to the helix to get it in the line of arch once it has extruded sufficiently so as not to interfere with the roots. The duration of this phase (duration of traction) will be calculated as the time between the application of the traction device and the alignment of the impacted canine.

3. Finishing: Orthodontic finishing of case to align the canine in the maxillary arch.

All surgical procedures will be carried out under local anesthesia by a single specialist (Oral and maxillofacial surgeon) having experience of practicing both surgical techniques: open and closed.

Open Surgical Exposure of Impacted canine:

- Surgically uncover the canine tooth and bone removal exposing the largest diameter of the ectopic canine crown. The edges need to be substantially trimmed back and dental follicle removed to prevent regrowth of the very thick palatal mucosa. For a deeply buried and palatally displaced tooth, the exposure will additionally need to be maintained using surgical pack.
- Coe-pack surgical dressing (GC America Inc, Alsip, IL) will be left in place.
- The patient will be reviewed 10 days later, the surgical pack will be removed and the bracket will be bonded and loading will be done by traction forces. Once the tooth has

erupted sufficiently for an orthodontic attachment to be positioned at its correct location to bring the tooth into line.

Closed Surgical Exposure of Impacted canine:

- Surgically, the palatal mucosal full thickness flap overlying the impacted canine will be raised and surgical bone removal exposing the largest diameter of the ectopic canine crown.
- An orthodontic attachment (button) with ligature wire and bracket with closed coil spring will be bonded to the palatal or buccal surface of the ectopic canine crown (whichever was the most accessible).

Outcome Assessment:

The following outcomes will be measured during and post orthodontic treatment:

Primary Outcome Measures:

1. Oral health based Quality of life of patients undergoing canine disimpaction will be accessed by questionnaire. (Annexure 1)

2. Measurement of width of attached gingiva. Measures which assess the periodontal outcome like crown length, gingival recession, bone will be assessed. (Annexure 2).

Secondary Outcome Measures:

3. Pain score on the visual analogue scale [Time Frame: 10 days post-surgery], many patient reported outcomes like the number of times the bond failure take place, surgical time, pain associated with surgery will be assessed. (Annexure 3)

4. EXPERIMENTAL SCHEDULE & OUTCOME FOR 3 YEARS:

Time in Months	1-2m	2-12m	12-30m	30-36m
Training of Research Associate and enrollment of patients				

Implementation of project and treatment phase				
Data Analysis and compilation of results				

5. **SHADOW PRICING OF PROPOSED STUDY & MODALITIES:** This is a routine fixed orthodontic procedure in Dept. of Orthodontics, Faculty of Dentistry, Jamia Millia Islamia and materials related to this project will be provided by the institute.

6. **SCIENTIFIC IMPACT OF PROPOSED STUDY:** According to present literature, there is no evidence to support either the open or the closed technique for exposing palatally ectopic canines to be clinically superior in terms of dental health, aesthetics, economics and patient factors. There is a high need for randomized clinical trials on this subject, the current literature provides very weak evidence. Current evidence gaps need to be filled. Our study aims at providing evidence as to which technique should be used to expose palatally impacted canines, open or closed. It will take into consideration the primary outcomes like periodontal health of the disimpacted teeth as well as the secondary outcomes that is the patient reported outcomes including patient comfort and aesthetics. This study might provide some good evidence which could help the surgeon and orthodontist to decide the suitable approach for a particular case.

7. **INSTITUTIONAL ETHICAL COMMITTEE CLEARANCE:**
   The project has received approval from Institutional ethical committee (IEC), Jamia Millia Islamia, New Delhi.

8. **MY SPECIFIC FUNCTION & ROLE IN THE PROPOSED STUDY:**
   After allocation of patients in both the groups, being an investigator, my role shall be clinical intervention from bonding the brackets to orthodontic dis-impaction of impacted canines to its normal position. Being a clinical research project, it will be

help in practicing both clinical, and research analysis. It will be a team effort i hope to contribute to the practice of evidence based dentistry through this project. By performing it to best of my abilities and minimizing bias.

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OUTCOME: Annexure 1;1

Oral Health Impact Profile Questionnaire (OHIP-14) (Pre-treatment)

S.no	Questions	Score (Tick any one)					
		Very Often	Fairly Often	Occasionally	Hardly ever	Never	Don't know
1.	Have you had trouble pronouncing any words because of problems with your teeth or mouth?	○	○	○	○	○	○
2.	Have you felt that your sense of taste has worsened because of problems with your teeth or mouth?	○	○	○	○	○	○
3.	Have you had painful aching in your mouth?	○	○	○	○	○	○
4.	Have you found it uncomfortable to eat any foods because of problems with your teeth or mouth?	○	○	○	○	○	○
5.	Have you been self-conscious because of your teeth or mouth?	○	○	○	○	○	○
6.	Have you felt tense because of problems with your teeth or mouth?	○	○	○	○	○	○
7.	Has been your diet been unsatisfactory because of problems with your teeth of mouth?	○	○	○	○	○	○
8.	Have you had to interrupt meals because of problems with your teeth or mouth?	○	○	○	○	○	○
9.	Have you found it difficult to relax because of problems with your teeth or mouth?	○	○	○	○	○	○
10.	Have you been a bit embarrassed because of problems with your teeth or mouth?	○	○	○	○	○	○
11.	Have you been a bit irritable with other people because of problems with your teeth or mouth?	○	○	○	○	○	○
12.	Have you had difficulty doing your usual jobs because of problems with your teeth or mouth?	○	○	○	○	○	○
13.	Have you felt that life in general was less satisfying because of problems with your teeth or mouth?	○	○	○	○	○	○
14.	Have you been totally unable to function because of problems with your teeth or mouth?	○	○	○	○	○	○

Annexure 1;2

Oral Health Impact Profile Questionnaire (OHIP-14) (Post-treatment)

S.no	Questions	Score (Tick any one)					
		Very Often	Fairly Often	Occasionally	Hardly ever	Never	Don't know
1.	Have you had trouble pronouncing any words because of problems with your teeth or mouth?	○	○	○	○	○	○
2.	Have you felt that your sense of taste has worsened because of problems with your teeth or mouth?	○	○	○	○	○	○
3.	Have you had painful aching in your mouth?	○	○	○	○	○	○
4.	Have you found it uncomfortable to eat any foods because of problems with your teeth or mouth?	○	○	○	○	○	○
5.	Have you been self-conscious because of your teeth or mouth?	○	○	○	○	○	○
6.	Have you felt tense because of problems with your teeth or mouth?	○	○	○	○	○	○
7.	Has been your diet been unsatisfactory because of problems with your teeth of mouth?	○	○	○	○	○	○
8.	Have you had to interrupt meals because of problems with your teeth or mouth?	○	○	○	○	○	○
9.	Have you found it difficult to relax because of problems with your teeth or mouth?	○	○	○	○	○	○
10.	Have you been a bit embarrassed because of problems with your teeth or mouth?	○	○	○	○	○	○
11.	Have you been a bit irritable with other people because of problems with your teeth or mouth?	○	○	○	○	○	○
12.	Have you had difficulty doing your usual jobs because of problems with your teeth or mouth?	○	○	○	○	○	○
13.	Have you felt that life in general was less satisfying because of problems with your teeth or mouth?	○	○	○	○	○	○
14.	Have you been totally unable to function because of problems with your teeth or mouth?	○	○	○	○	○	○

Annexure 1;3

Oral Health related Quality of life Questionnaire

(24hrs after surgery)

How much trouble you have with your teeth or mouth?

S.no	Questions	Score (Tick any one)				
		No trouble	A little trouble	Some trouble	Quite a lot trouble	Lots of trouble
1.	Eating/chewing foods you want	○	○	○	○	○
2.	Opening your mouth wide	○	○	○	○	○
3.	Sleeping	○	○	○	○	○
4.	Talking to people so that they can understand you	○	○	○	○	○
5.	Going about your everyday routine	○	○	○	○	○
6.	Taking part in your social life	○	○	○	○	○
7.	Taking part in sports	○	○	○	○	○
8.	Swelling of your cheeks	○	○	○	○	○
9.	Bruising	○	○	○	○	○
10.	Bleeding	○	○	○	○	○
11.	Nausea	○	○	○	○	○
12.	Bad taste / bad breath	○	○	○	○	○
13.	Food collecting in the hole after the teeth were pulled	○	○	○	○	○
14.	Rate the worst pain you have felt in your teeth, mouth and face during past 24 hrs.	1	2	3	4	5

Annexure 1;4

Oral Health related Quality of life Questionnaire

(Ten days after surgery)

How much trouble you have with your teeth or mouth?

S.no	Questions	Score (Tick any one)				
		No trouble	A little trouble	Some trouble	Quite a lot trouble	Lots of trouble
1.	Eating/chewing foods you want	○	○	○	○	○
2.	Opening your mouth wide	○	○	○	○	○
3.	Sleeping	○	○	○	○	○
4.	Talking to people so that they can understand you	○	○	○	○	○
5.	Going about your everyday routine	○	○	○	○	○
6.	Taking part in your social life	○	○	○	○	○
7.	Taking part in sports	○	○	○	○	○
8.	Swelling of your cheeks	○	○	○	○	○
9.	Bruising	○	○	○	○	○
10.	Bleeding	○	○	○	○	○
11.	Nausea	○	○	○	○	○
12.	Bad taste / bad breath	○	○	○	○	○
13.	Food collecting in the hole after the teeth were pulled	○	○	○	○	○
14.	Rate the worst pain you have felt in your teeth, mouth and face during past 24 hrs.	1	2	3	4	5
15.	Are you still taking any pain killers? (yes/no)					
16.	If yes, How many days you took and frequency					

2. CLINICAL OUTCOMES (Annexure 2)

(To be measured after 1 month post debond):

Group: open/closed	
1. Pocket Depth	
2. KT width	
3. a. Gingival recession, if any, measured on the buccal midpoint of the canine crown. b. Gingival recession, if any, measured on the buccal midpoint of the L.I. crown.	
4. Clinical crown length-incisal edge to gingival margin on midfacial surface parallel to the long axis.	
5. Clinical crown length-incisal edge to gingival margin on midfacial surface parallel to the long axis of the contralateral tooth	
6. Time period it took to align	DOE DOA
7. How many times did bracket debond	
8. How many times flap was raised.	
9. Probing bone level-subtracting the distance CEJ to gingival margin from the distance gingival margin to bone.	
10. Bleeding on probing	
11. Loe and silness score	

Operator's measure of surgical ease (Annexure 3)

Group (open/closed):

S.NO.	QUESTION	
1.	Actual surgical time- from incision to last suture	
2.	Difficulties felt by Operator	
3.	Number of times flap was raised	
4.	No of times button debonded	
5.	Duration of traction phase till alignment of canine	

Maxillary Canine Aesthetic Index scoring sheet

(Annexure 4)

Patient name: ……..
Date of recording: ……..
Working side: ……..

Parameters investigating the previously impacted canine			
	Absent	Incomplete	Complete
Mesial papilla			
Distal papilla			
Marginal gingiva			
Recession			
Marginal gingival thickness			
Mesiodistal canine angulation			

Parameters investigating comparison between both canines			
	Major discrepancy	Minor discrepancy	No discrepancy
Curvature of marginal gingiva			
Soft tissue color and texture			
Root convexity			
Tooth morphology			
Vertical tooth position			
Parameters investigating relation previously impacted canine and neighboring teeth			
Bucco-lingual angulation crown acc. neighboring teeth			

Total score 0–3 points = excellent
4–8 points = good
9–13 points = moderate
14 or more points = poor aesthetics
Total score =

Baseline Data

Patient's name:

Age/sex:

UID no:

Case no:

Contact number:

Address:

Side of Impaction

Severity of Impaction (Ericson and Kurol)

Angle:

Vertical height:

Sector:

Oral Hygiene:

Date of start of fixed treatment:

Date of surgical exposure:

Date of alignment of canine:

Date of debonding:

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(A Central University by an Act of Parliament)
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دفتر مسجّل

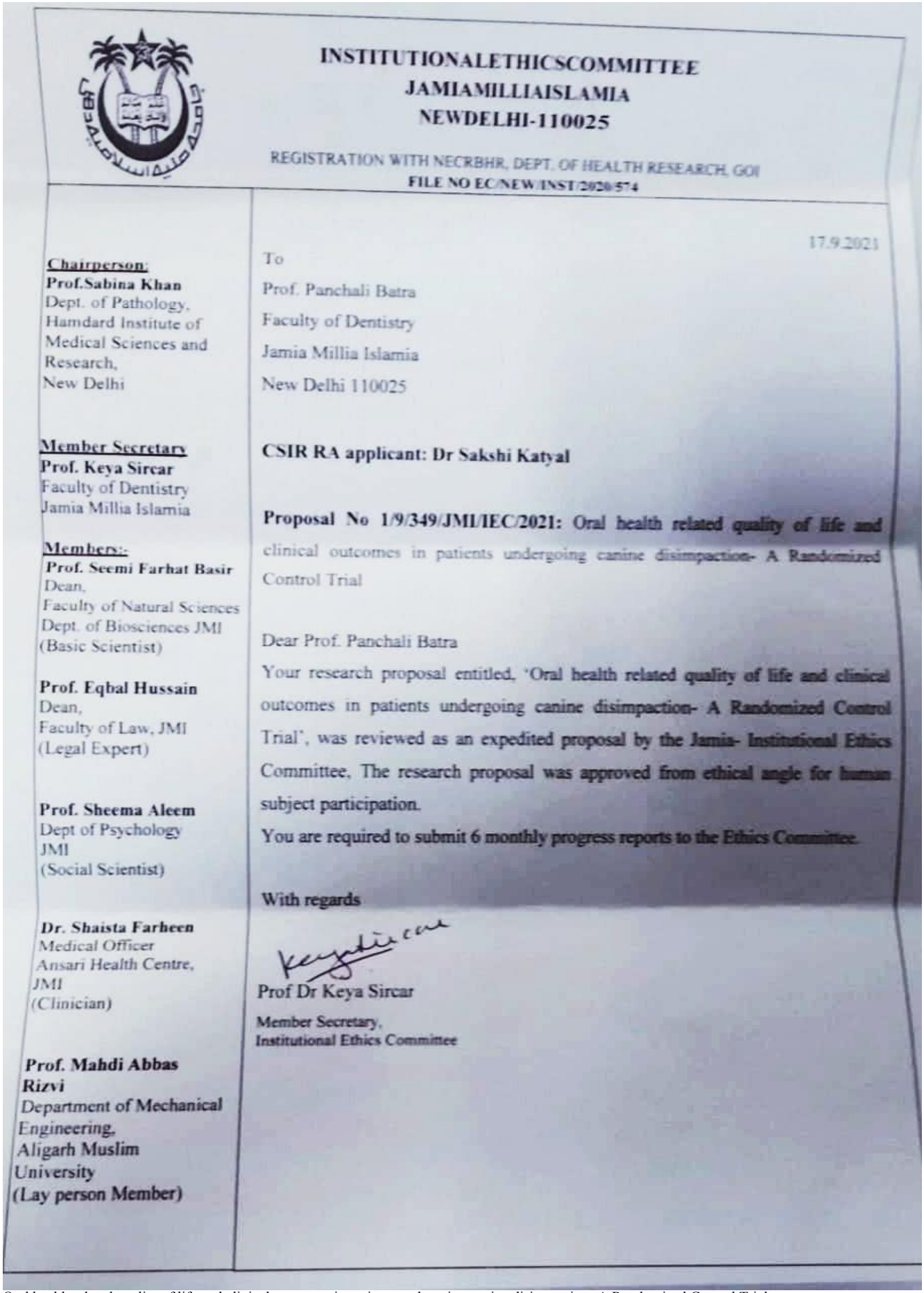
جامعہ ملیہ اسلامیہ

Date: 09.09.2021

To whom it may concern

This is to certify that JMI has no objection on the project titled "Oral health related quality of life, clinical and radiographic outcomes in patients undergoing canine disimpaction – A randomised Control Trial."to be conducted in Deptt. of Orthodontics, Faculty of Dentistry, JMI by Dr. Sakshi under **CSIR SRA Scheme.**

(Dr. Nazim Husain Jafri)
Registrar



INSTITUTIONALETHICSCOMMITTEE
JAMIAMILLIAISLAMIA
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REGISTRATION WITH NECRBHR, DEPT. OF HEALTH RESEARCH, GOI
FILE NO EC/NEW/INST/2020/574

17.9.2021

To
Prof. Panchali Batra
Faculty of Dentistry
Jamia Millia Islamia
New Delhi 110025

CSIR RA applicant: Dr Sakshi Katyal

Proposal No 1/9/349/JMI/IEC/2021: Oral health related quality of life and clinical outcomes in patients undergoing canine disimpaction- A Randomized Control Trial

Dear Prof. Panchali Batra

Your research proposal entitled, 'Oral health related quality of life and clinical outcomes in patients undergoing canine disimpaction- A Randomized Control Trial', was reviewed as an expedited proposal by the Jamia- Institutional Ethics Committee, The research proposal was approved from ethical angle for human subject participation.

You are required to submit 6 monthly progress reports to the Ethics Committee.

With regards

Prof Dr Keya Sircar
Member Secretary,
Institutional Ethics Committee

Oral health related quality of life and clinical outcomes in patients undergoing canine disimpaction- A Randomized Control Trial.

NCT number: NCT01917604

Institutional Ethics Committee (IEC)

Jamia Millia Islamia

Annexure III (Subject Information Sheet and Consent Form for Patients)

Title of the project:

Oral health related quality of life, clinical outcomes in patients undergoing canine disimpaction- A Randomized Control Trial.

Site of the investigation:

Department of Orthodontics, Oral surgery and Periodontology, Faculty of Dentistry, Jamia Millia Islamia, New Delhi, 110025

Name, address and contact number of the Principal Investigators:

Dr. Panchali Batra

Professor,

Department of Orthodontics.

Contact 9999908022

Aims and methods of the research

The permanent canine or corner tooth in the upper arch usually erupts by the age of 11-12 years. Sometimes, this tooth may not erupt in the oral cavity and may remain impacted inside the bone. This tooth has the longest root, supports the corners of the mouth and helps to protect other teeth during function hence it is very important to save this tooth and do every effort to save or align/disimpact this tooth. Leaving this tooth in the bone might sometimes lead to unfavourable consequences like root resorption of the adjacent teeth or development of cysts. To align this tooth in the arch, the patient needs fixed braces treatment so that traction force can be applied to the tooth. Since this tooth impacted, is covered by soft tissue or bone, and is not visible in the oral cavity, the tooth has to be uncovered by a minor surgical

procedure so that the bracket can be placed on that tooth and then traction force could be applied. There are 2 commonly used methods of exposing the tooth surgically-open surgical method in which the tooth remains open and visible in the oral cavity throughout the alignment period, and the closed method in which the flap is restored back and tooth is not visible. Since there is lack of high quality evidence as to which surgical approach is better, it is left to the discretion of the surgeon to select the surgical method of exposure. This study aims to evaluate the difference in the results of the two methods by assessing the clinical and patient related outcomes. The patients will be randomly divided into the two groups. Both the surgical procedures are routine procedures applied for disimpaction. An oral health related quality of life related to experiences of patient undergoing disimpaction will be collected by a written questionnaire format.

1. Expected duration of the subject participation.

Three years

2. The benefits to be expected from the research to the subject or to others.

Our research project will help us improve our understanding as to which method of surgical treatment is better and will be evidence based. This will help the clinician to give clear indications for each surgical method and may benefit patients as repeated trauma due to surgeries could be avoided. Also patient with impacted canine will benefit from its alignment in arch for better function and aesthetics.

3. Alternative treatment/procedure options.

These are the only two surgical methods followed, there are no alternatives.

4. Right to prevent use of biological samples (DNA, cell line etc.) at any time during the research.

Not applicable as no biological samples as DNA, Cell line are collected in this study.

5. Any risk to the subject associated with the study.

There are no major health risks of taking part in this study as it's a conventional procedure of disimpaction. Through this research we intend to only observe the features of both the techniques and these are being practiced as standard procedures. We do not anticipate any major threat to life and health because of this treatment.

6. Maintenance of confidentiality of records.

All the personal information of the patient that is collected during the course of the research will be kept strictly confidential. The data regarding results of the study will be used for publication without disclosing identity of the subjects.

7. Provision of free treatment for research related injury.

There is no anticipation of any additional risks or injury related to research project. In the event of a bodily injury or illness directly resulting from the study, the institute will give reasonable and necessary treatment. 'Jamia Millia Islamia' is not responsible for medical expenses due to pre-existing medical conditions, any underlying diseases, any ongoing treatment process and negligence or willful misconduct of the patient or investigator.

8. Compensation of subjects for disability or death resulting from such injury.

We do not anticipate any disability or death from this research procedure.

9. Freedom of individual to participate or to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.

You are free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

10. Amount of clinical sample in quantity, to be taken should be mentioned.

No clinical sample (eg. blood, urine, sputum) is collected from patient for this study, only clinical observations are made in this study.

11. Source of funding for the Investigation.

Nothing additional will be charged from patient for research project. The patients will be charged by institute as per its existing subsidised charges for dental treatment.

12. In case of drug trials:

a) **The chemical name of drug, date of its manufacturing and batch number must be mentioned -** Not applicable

b) Initial bio equivalent study of the drug/references should be provided - Not applicable.

13. Foreseeable extent for information on possible current and future usage of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, clear mention of the same.

The data generated from this research may be used for research publication purposes but identity of individual and sensitive personal information will be kept confidential. Data will not be put to any secondary purpose.

14. Risk of discovery of biologically sensitive information.

Biological sensitive information will be kept confidential.

15. Publication, if any, including photographs and pedigree charts.

At the end of the study all the information will be put together and the results will be presented and published in a peer reviewed journal and confidentiality of the patient personal information will be maintained.

Responsibility of Investigators.

Investigators take the responsibility that your treatment will not be changed or altered in any way because you are in this study. Also all your records shall be kept confidential and will not be revealed to any outsider.

Consent

1. I agree voluntarily to take part in this study.
2. I have been explained the purpose and other details of the study. I have been given a full explanation of the procedures involved.
3. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction.
4. I am free to withdraw from the study at any time without any reason and without my medical care or legal right being affected.
5. I understand that the information in my medical records is essential to evaluate the results of the study. I agree to release this information on the understanding that will be treated confidentially.
6. I agree that I will not be referred to by name in any reports/documents/any other means concerning this study.
7. I have been explained the risks and benefits for the patients and society associated with the study.
8. I agree that if I am harmed as result of taking part in the study, treatment will be provided free of cost by the PI/Institution/University.
9. I agree/ do not agree that the data collected during this study may be stored for future use.

I willingly agree to take part in the above study.

Signature of the participant/guardian Date:
Name:
Age:
Address:

Signature of the doctor/Principal Investigator: Date:

Signature of the witness: Date:

Signature page for patients between ages 13 - 17 years of age:

1. I agree that my child is voluntarily taking part in this study.
2. I have been explained the purpose and other details of the study. I have been given a full explanation of the procedures involved.
3. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction.
4. I know that my child is free to withdraw from the study at any time without any reason and without my medical care or legal right being affected.
5. I understand that the information in my child's medical records is essential to evaluate the results of the study. I agree to release this information on the understanding that will be treated confidentially.
6. I agree that my child will not be referred to by name in any reports/documents/any other means concerning this study.
7. I have been explained the risks and benefits for the patients and society associated with the study.
8. I agree that if my child is harmed as result of taking part in the study, treatment will be provided free of cost by the PI/Institution/University.
9. I agree/ do not agree that the data collected during this study may be stored for future use

I willingly agree that my child will take part in the above study.

Signature of the parent/guardian Date:

Assent of child: ---------- (name of child/minor) has agreed to participate in above study

Signature of the child Date:

Name:
Age:
Address:

Signature of the doctor/Principal Investigator: Date:

Signature of the witness: Date:

Institutional Ethics Committee (IEC)

JamiaMilliaIslamia

Annexure III (Subject Information Sheet and Consent Form for Patients in Hindi)

परियोजना का शीर्षक:

कैनाइन विच्छेदन के दौर से गुजर रहे रोगियों में मौखिक स्वास्थ्य से संबंधित जीवन की गुणवत्ता, नैदानिक परिणाम- एक यादृच्छिक नियंत्रण परीक्षण।

जांच के साइट:

दंत चिकित्सा के ओर्थोडोंटिक विभाग, संकाय, जामिया मिलिया इस्लामिया, नई दिल्ली, 110025

नाम, पता और प्रधान जांचकर्ता के संपर्क नंबर:

डॉ पांचाली बत्रा
प्रोफेसर,
ओर्थोडोंटिक विभाग।
संपर्क 9999908022

लक्ष्य और अनुसंधान के तरीके

मुँह की छत में फसे कैनाइन दांत को बेनकाब करने के लिए एक खुली या बंद शल्य चिकित्सा पद्धति में कोई मतभेद नही है । परीक्षण के लिए प्रतिभागियों को उपचार प्रतीक्षा सूची और नए मरीज क्लीनिक से पहचाना जाएगा। खुली या बंद शल्य चिकित्सा पद्धति: वे बेतरतीब ढंग से दो समूहों में आवंटित किया जाएगा। मरीज के मुंह के अन्य वृत्त का चतुर्थ भाग नियंत्रण के रूप में कार्य करेगा।

एक तकनीक में फ्लैप उठाया जाएगा अटैचमेंट बॉधा जाएगा और फिर फ्लैप फिर से वापस सीवन किया जाएगा।अन्य तकनीक में फ्लैप उठाया जाएगा और एक खिड़की बनाया जाए गी और अटैचमेंट बाद में बॉधा जाएगा । इलाज पूरा हो गया है जब तक रोगी की समीक्षा की जाएगी। रोगी को जीवन की मौखिक स्वास्थ्य गुणवत्ता से संबंधित एक प्रश्नावली भरने के लिए कहा जाएगा.

1.विषय भागीदारी की अनुमानित अवधि।

3 साल

2. अनुसंधान के लाभ

हमारी शोध परियोजना से हमें यह समझने में मदद मिलेगी कि सर्जिकल उपचार का कौन सा तरीका बेहतर है और साक्ष्य आधारित होगा। इससे चिकित्सक को प्रत्येक शल्य चिकित्सा पद्धति के लिए स्पष्ट संकेत देने में मदद मिलेगी और रोगियों को लाभ हो सकता है क्योंकि सर्जरी के कारण बार-बार होने वाले आघात से बचा जा सकता है। इसके अलावा प्रभावित कैनाइन वाले रोगी को बेहतर कार्य और सौंदर्यशास्त्र के लिए आर्च में इसके संरेखण से लाभ होगा।

3. वैकल्पिक उपचार / प्रक्रिया विकल्प।

कोई नहीं। केवल ये दो शल्य चिकित्सा पद्धतियों का पालन किआ जाता है ।

1. शोध के दौरान किसी भी समय जैविक नमूने (डीएनए, सेल लाइन आदि) के उपयोग को रोकने का अधिकार:

लागू नहीं है क्योंकि इस अध्ययन में डीएनए, सेल लाइन के रूप में कोई जैविक नमूने एकत्र नहीं किए गए हैं।

5. अध्ययन से जुड़े विषय के लिए किसी भी प्रकार का जोखिम:

इस अध्ययन में भाग लेने का कोई बड़ा स्वास्थ्य जोखिम नहीं है क्योंकि यह एक पारंपरिक प्रक्रिया है। इस शोध के माध्यम से हम केवल दोनों तकनीकों की विशेषताओं का निरीक्षण करना चाहते हैं और इन्हें मानक प्रक्रियाओं के रूप में अभ्यास किया जा रहा है। हम इस उपचार के कारण जीवन और स्वास्थ्य के लिए किसी बड़े खतरे की आशंका नहीं रखते हैं।

6.रिकॉर्ड की गोपनीयता:

रोगी की सभी व्यक्तिगत जानकारी जो अनुसंधान के दौरान एकत्र की जाती है उसे कड़ाई से गोपनीय रखा जाएगा। अध्ययन के परिणामों से संबंधित डेटा का उपयोग विषयों की पहचान का खुलासा किए बिना प्रकाशन के लिए किया जाएगा।

7.अनुसंधान से संबंधित चोट लगने पर मुफ्त इलाज का प्रावधान:

अनुसंधान परियोजना से संबंधित किसी भी अतिरिक्त जोखिम या चोट की कोई आशंका नहीं है। अध्ययन के परिणामस्वरूप सीधे शारीरिक चोट या बीमारी की स्थिति में, संस्थान उचित और आवश्यक उपचार देगा। 'जामिया मिलिया इस्लामिया' पहले से मौजूद चिकित्सा स्थितियों, किसी अंतर्निहित बीमारी, किसी भी चल रही उपचार प्रक्रिया और लापरवाही या रोगी या अन्वेषक की जानबूझकर कदाचार के कारण चिकित्सा खर्चों के लिए जिम्मेदार नहीं है।

8. इस तरह की चोट से उत्पन्न विकलांगता या मौत के लिए विषयों का मुआवजा।

हम इस शोध से किसी विकलांगता या मृत्यु का अनुमान नहीं लगाते हैं।

9. किसी भी समय अनुसंधान में भाग नहीं लेने की व्यक्ति की स्वतंत्रता बिना किसी जुर्माना या लाभ की हानि के, जिसके विषय अन्यथा हकदार होंगे।

यह अध्ययन स्वैच्छिक है; यह तय करना आप पर निर्भर है। अगर आप भाग लेने के लिए मना कर दें तो इस से आपके देखभाल या उपचार पर असर नहीं होगा। अगर आप भाग लेने का फैसला करते है तबभी आप किसी भी समय बिना कारण अध्ययन मे ना भाग लेने के लिए स्वतंत्र हैं।

10. अनुसंधान मे भाग लेने वाले मरीजों की संख्या

इस अध्ययन के लिए रोगी से कोई नैदानिक नमूना (जैसे रक्त, मूत्र, थूक) एकत्र नहीं किया जाता है, इस अध्ययन में केवल नैदानिक अवलोकन किए जाते हैं।

11. जांच के लिए धन का स्रोत।

अनुसंधान परियोजना के लिए रोगी से कोई अतिरिक्त शुल्क नहीं लिया जाएगा। दंत चिकित्सा के लिए मौजूदा रियायती शुल्क के अनुसार संस्थान द्वारा रोगियों से शुल्क लिया जाएगा

12.दवा परीक्षण के मामले में:

a) दवा का रासायनिक नाम इसके निर्माण की तिथि और बैच नंबर

b) दवा की प्रारंभिक जैव समकक्ष अध्ययन संदर्भ / प्रदान की जानी चाहिए

लागू नहीं

13. जैविक सामग्री के संभावित वर्तमान और भविष्य के उपयोग

इस शोध से उत्पन्न डेटा का उपयोग शोध प्रकाशन उद्देश्यों के लिए किया जा सकता है लेकिन व्यक्तिगत और संवेदनशील व्यक्तिगत जानकारी की पहचान गोपनीय रखी जाएगी। डेटा को किसी द्वितीयक उद्देश्य के लिए नहीं रखा जाएगा।

14. जैविक रूप से संवेदनशील जानकारी की खोज का जोखिम।

जैविक संवेदनशील जानकारी को गोपनीय रखा जाएगा।

15. प्रकाशन किसी भी फोटो और वंशावली चार्ट के सहित ।

अध्ययन के अंत में सभी जानकारी एक ओथडोटिक जर्नल में एक साथ डाल दीजाएगी और परिणाम प्रस्तुत किया जाएगा। आप के बारे में किसी भी जानकारी को प्रकाशित करने के समय अप का नाम और पता हटा दिया जाएगा।

16.जांचकर्ताओं की जिम्मेदारी।

जांचकर्ता जिम्मेदारी लेते हैं कि यदि आप इस अध्ययन में हैं तो किसी भी तरह से इलाज परिवर्तित या बद ला नहीं जाएगा। सब के रिकॉर्ड गोपनीय ररवे जाएगे और किसी भी बाहरी व्यक्ति को नहीं बताया जाएगा।

मरीजों के लिए सहमति पत्र) उम्र 18 और उससे अधिक)

सहमति

1. मैं इस अध्ययन में भाग लेने के लिए स्वेच्छा से सहमत हूं
2. मुझे अध्ययन का उद्देश्य और अन्य विवरण समझाया गया है। मुझे इसमें शामिल प्रक्रियाओं का पूरा विवरण दिया गया है
3. मुझे सवाल पूछने का मौका दिया गया है और मेरे सभी सवालों का जवाब मेरी संतुष्टि के लिए दिया गया है

4. मैं बिना किसी कारण के किसी भी समय अध्ययन से पीछे हटने के लिए स्वतंत्र हूं और मेरी चिकित्सा देखभाल या कानूनी अधिकार प्रभावित हुए बिना
5. मैं समझता हूं कि अध्ययन के परिणामों का मूल्यांकन करने के लिए मेरे मेडिकल रिकॉर्ड में जानकारी आवश्यक है। मैं इस जानकारी को उस समझ पर जारी करने के लिए सहमत हूं जिसे गोपनीय रूप से माना जाएगा
6. मैं इस बात से सहमत हूं कि मुझे इस अध्ययन से संबंधित किसी भी रिपोर्ट / दस्तावेज / किसी अन्य माध्यम से नाम से संदर्भित नहीं किया जाएगा
7. मुझे अध्ययन से जुड़े रोगियों और समाज के लिए जोखिम और लाभ के बारे में समझाया गया है
8. मैं इस बात से सहमत हूं कि यदि मुझे अध्ययन में भाग लेने के परिणामस्वरूप नुकसान हुआ है, तो पीआई / सतर्कता / विश्वविद्यालय द्वारा उपचार नि: शुल्क प्रदान किया जाएगा।
9. मैं इस बात से सहमत हूं कि इस अध्ययन के दौरान एकत्र किए गए आंकड़े को भविष्य में उपयोग के लिए संग्रहीत किया जा सकता है।

मैं स्वेच्छा से उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं।

अनुमति दे अनुमति नहीं दे

प्रतिभागी / अभिभावक का हस्ताक्षर दिनांक:

नाम:

उम्र:

पता:

डॉक्टर / प्रधान अन्वेषक का हस्ताक्षर: दिनांक:

साक्षी का हस्ताक्षर: दिनांक

13 वर्ष से 17 वर्ष की आयु के बच्चों को शामिल करने के लिए हस्ताक्षर पृष्ठ

1. मैं इस बात से सहमत हूं कि मेरा बच्चा स्वेच्छा से इस अध्ययन में भाग ले रहा है।

2. मुझे अध्ययन का उद्देश्य और अन्य विवरण समझाया गया है। मुझे इसमें शामिल प्रक्रियाओं का पूरा विवरण दिया गया है
3. मुझे सवाल पूछने का मौका दिया गया है और मेरे सभी सवालों का जवाब मेरी संतुष्टि के लिए दिया गया है
4. मुझे पता है कि मेरा बच्चा बिना किसी कारण के किसी भी समय अध्ययन से पीछे हटने के लिए स्वतंत्र है और मेरी चिकित्सा देखभाल या कानूनी अधिकार प्रभावित हुए बिना

5. मैं समझता हूं कि अध्ययन के परिणामों का मूल्यांकन करने के लिए मेरे बच्चे के मेडिकल रिकॉर्ड में जानकारी आवश्यक है। मैं इस जानकारी को उस समझ पर जारी करने के लिए सहमत हूं जिसे गोपनीय रूप से माना जाएगा।

6. मैं इस बात से सहमत हूं कि मेरे बच्चे को इस अध्ययन से संबंधित किसी भी रिपोर्ट / दस्तावेज / किसी अन्य माध्यम से नाम से नहीं भेजा जाएगा

7. मुझे अध्ययन से जुड़े रोगियों और समाज के लिए जोखिम और लाभ के बारे में समझाया गया है
8. मैं इस बात से सहमत हूं कि यदि मेरे बच्चे को अध्ययन में भाग लेने के परिणामस्वरूप नुकसान हुआ है, तो पीआई / संस्थान / विश्वविद्यालय द्वारा मुफ्त में उपचार प्रदान किया जाएगा।

9. मैं इस बात से सहमत हूं कि इस अध्ययन के दौरान एकत्र किए गए आंकड़े को भविष्य में उपयोग के

लिए संग्रहीत किया जा सकता है।

मैं स्वेच्छा से सहमत हूं कि मेरा बच्चा उपरोक्त अध्ययन में भाग लेगा।

अनुमति दे अनुमति नहीं दे

माता-पिता / अभिभावक का हस्ताक्षर

दिनांक:

नाम:

उम्र:

पता:

बच्चे की सहमति: ---------- बच्चे / नाबालिग का नाम) उपरोक्त अध्ययन में भाग लेने के लिए सहमत हो गया है

बच्चे का हस्ताक्षर दिनांक:

डॉक्टर / प्रधान अन्वेषक का हस्ताक्षर: दिनांक:

साक्षी का हस्ताक्षर: दिनांक