Official Title:

Posterior slab vs total contact cast in diabetic foot ulcers: a randomised controlled trial

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PROTOCOL

ILSS/EC/0012-DFU/2022

POSTERIOR SLAB VS TOTAL CONTACT CAST IN DIABETIC FOOT ULCERS: A RANDOMISED CONTROLLED TRIAL

ILS Hospital, DD-6, Sector-1, Salt Lake, Kolkata-700064, West Bengal

Table of Contents

1. AFFILIATIONS

Research Institute

ILS Hospital, Salt Lake.
Address: DD-6, Sector 1, Salt Lake City, Kolkata-700064

Principal Investigator-cum-Guide **:** Dr. Ghanshyam Goyal
Address: **ILS Hospital, Salt Lake**,
DD-6, Sector 1, Salt Lake City, Kolkata-700064
Phone Number: +91-9830400450
Email: drgsgoyal@hotmail.com

Co-Guide **:** Dr. Rekha Srivastav
Address: **ILS Hospital, Salt Lake**,
DD-6, Sector 1, Salt Lake City, Kolkata-700064
Phone Number: +91-9831058704
Email: ins.rekha@gmail.com

2. INTRODUCTION

There are three basic principles in the management of diabetic foot ulcer (DFU) – adequate debridement and infection control, adequate vascularity, and adequate offloading. Off-loading of the ulcer area is extremely important for the healing of neuropathic plantar ulcers. Total Contact Cast (TCC) remains the gold standard treatment of Diabetic Foot Ulcer (DFU). However, there are many practical problems associated with TCC, including local skin irritation, worsening of deformed toe nails, fungal infections, claustrophobia, joint rigidity, atrophy of the smaller foot muscles, postural instability and painful leg and calf muscles. So, TCCs are underutilized in clinical practice as they are technically difficult and time consuming to apply, relatively expensive and have low patient tolerance. Their use is also contraindicated in patients with infected or ischaemic ulcers. Posterior slab cast (PSC) is also a good offloading modality in neuropathic DFU. It can be more convenient and economical as a single slab can be used till complete healing is achieved. Thus may provide a lesser invasive way of immobilization of the foot in DFU.

3. AIM & OBJECTIVES

Aim of this trial is to compare the efficacy of Posterior slab cast (PSC) with Total Contact cast (TCC) in terms of wound healing and foot related outcomes in patients having neuropathic planter diabetic foot ulcers in a tertiary care diabetic foot clinic.

4. INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria

1. Type 2 Diabetes Mellitus
2. Having solitary neuropathic plantar ulcer
3. Ulcer belonging to Wagner's grade 2 or 3

Exclusion criteria

1. Persons with bilateral DFUs
2. Peripheral vascular disease (ABI < 0.9)
3. Gout
4. steroid intake in the last three months,
5. Stage 4 & 5 chronic kidney disease with estimated glomerular filtration rate (eGFR) <30 ml/min/m2,
6. Bilateral foot involvement,

5. MATERIAL & METHODS

It is an open label randomized control trial. It will be done in ILS Hospital, Kolkata for a trial period of around 3 years.

Diabetic patients attending the foot clinic with plantar ulcer irrespective of age, sex, glycemic control, duration of diabetes, duration of ulcer and presence of infection will be considered for the study. At first patients will be randomly allocated to any one of two off-loading procedures using the randomization table: TCC or PSC. Those who will refuse TCC, will be shifted to PSC group. All patients will be followed up at the foot clinic once in two weeks' basis for device inspection, wound care and wound debridement as and when indicated. After the completion of treatment, all the patients will be followed up to 15 months from the initiation of treatment to identify any recurrence of ulcer.
Two outcome measures will be used. The primary outcome measure is healing of the ulcer after 8 months. The secondary outcome measure is to document which of the device is associated with comparatively better healing at 6 months.

6. OUTLINE OF TIME PLANS:

Proposed date of starting research activity: January 2023
Expected duration of research activity: 1.5 years
Undertaking to provide interim report of the work halfway through it: Yes
Undertaking to provide full report of the work on completion: Yes

7. STATISTICAL ANALYSIS:

Comparison will be done between the two groups. Continuous variables will be compared by t-tests and categorical variables by chi-square test. Baseline comparison will be made using chi-square tests and two-sample t-tests. Continuous variables will be expressed as mean (standard deviation). The differences in pertinent characteristics will be established with the use of t-test for independent samples. A two-sided p value of 0.05 was considered statistically significant.

8. ETHICS

01) Subject information brochure: Yes
02) Informed consent form: Yes
03) Statement of conflict of interest, if any: None

Publication-plans for the outcome (positive or negative) while maintaining the privacy and confidentiality of the study participants:

The privacy and confidentiality of the study participants will be maintained in all publications/reports originating from this study.

9. SOURCE(S) OF FUNDING:

Not Applicable

10. PRIMARY REFERENCES:

1) A mouldable fibreglass backslab device as a novel approach to offload chronic plantar foot ulcers: A retrospective observational audit; First published: 21 August, 2024,https://doi.org/10.1002/jfa2.70001
2) Li B, Lin A, Huang J, Xie J, Liu Q, Yang C, Zhang Z. Total contact casts versus removable offloading interventions for the treatment of diabetic foot ulcers: a systematic review and meta-analysis. Front Endocrinol (Lausanne). 2023 Sep 26;14:1234761. doi: 10.3389/fendo.2023.1234761. PMID: 37822605; PMCID: PMC10562689
3) A Comparative Study Between Total Contact Cast and Pressure-Relieving Ankle Foot Orthosis in Diabetic Neuropathic Foot Ulcers; Partha Pratim Chakraborty et al; Journal of Diabetes Science and Technology 2015, Vol. 9(2) 302 –308 © 2014 Diabetes Technology Society Reprints and permissions: sagepub.com/journalsPermissions.nav DOI: 10.1177/1932296814560788

11. COPY OF THE CONSENT FORMS:

POSTERIOR SLAB VS TOTAL CONTACT CAST IN DIABETIC FOOT ULCERS: A RANDOMISED CONTROLLED TRIAL

Study to be conducted by: **Dept of Diabetology & Diabetic Foot Clinic, ILS Hospitals, Saltlake**

You are being invited to participate in a clinical research trial. The following information is for you to understand why the research is being done and what it will involve. Please take time to read it carefully and discuss with friends, relatives and your family doctor if you wish. Please feel free to ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Please sign the Informed Consent Form only if you are fully satisfied with the information given to you and you understand the procedures involved in the study.

What is the purpose of the trial?

Aim of this trial is to compare the efficacy of Posterior slab cast (PSC) with Total Contact cast (TCC) in terms of wound healing and foot related outcomes in patients having neuropathic planter diabetic foot ulcers in a tertiary care diabetic foot clinic.

Why have I been chosen?

Diabetic patients having solitary neuropathic plantar ulcer have been chosen for the study. You have been selected because you have an foot ulcer and also satisfy the other selection criteria for the study.

Do I necessarily have to take part?

No, it is up to you to decide whether or not to take part. If you decide to take part, you will be asked to sign a consent form. Even after you have decided to take part, you are still free to withdraw anytime you choose without giving us a reason. A decision to withdraw, or a decision not to take part, will not affect the quality of care you receive.

What happens during the study?

If you agree to participate, no extra intervention will be done and neither any special drugs will be used. We will use the post-trial data generated for a clinical research purpose.

Are there any other possible disadvantages of taking part?

No disadvantages since the data generated post-trial will be used for research purpose.

Will my taking part in this study be kept confidential?

Yes. All data obtained from the study will be kept confidential. The data would be archived for an appropriate period. This data will be used only by authorized persons for scientific purposes.

What will happen to the results of the study?

A study report will be finalized soon after the trial closes. This will be submitted to the ethics committee of the institute carrying out the study, and also to government authorities if needed. The results may be published in a scientific journal or discussed at a scientific forum. You will however, not be identified in any report / publication.

Contact for further information:

The doctors conducting this study can discuss it in more detail with you and reply to any query, when it arises. The contact persons are:

Dr. Ghanshyam Goyal Principal Investigator ILS Hospital, Saltlake DD-6, Sector-1, Salt Lake City, Kolkata - 700064 Ph No:+91-983040450 Email: drgsgoyal@hotmail.com	Dr. Rekha Srivastav Co-Guide ILS Hospital, Saltlake DD-6, Sector-1, Salt Lake City, Kolkata - 700064 Ph No: +91-9831058704 Email: ins.rekha@gmail.com
Principal Investigator - cum - Guide	***Co-Guide***

Thank you for going through the Patient Information Sheet.

Should you decide to participate in this clinical study, we thank you for that too.

INFORMED CONSENT FORM

POSTERIOR SLAB VS TOTAL CONTACT CAST IN DIABETIC FOOT ULCERS: A RANDOMIED CONTROLLED TRIAL

Patient's: Name: _____Initials _____Age _____Sex _____

1. I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions. [ ]

2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without having to give a reason, and without my medical care or legal rights being affected. [ ]

3. I understand that my data would be kept confidential but individuals authorized by the Principal Investigator, the ethics committee of the institute where the study will be conducted and government drug regulatory authority will have access to my health records both in respect of the current study and further research that may be conducted in relation to it. Even if I withdraw, I agree to this access. However, I understand that my identity will not be revealed and confidentiality of information will be maintained. [ ]

4. I agree not to restrict the authorized use of any data or results that arise From this study. [ ]

5. I agree to voluntarily take part in the above study. [ ]

Signature / Thumb impression of the subject: _____

Date: _____Place: _____

Study doctor's name: _____

Study doctor's signature: _____Date: _____Place: _____

Mandatory where subject has provided thumb impression:

Signature of the witness:_____

Date: _____Place:_____

Name & Address of the witness:_____

_____

Relation to the subject, if any:_____

12. COPY OF HISTORY FILE

POSTERIOR SLAB VS TOTAL CONTACT CAST IN DIABETIC FOOT ULCERS: A RANDOMIED CONTROLLED TRIAL

CASE REPORT FORMS

TO BE FILLED AT THE TIME OF FIRST OP VISIT

ILS HOSPITALS

DIABETES & OBESITY CLINIC
(ASSESSMENT FORM)

Date..... UHID No. .....

1. Patient Details :

Name : .....Age : ..... Sex : Male / Female

Address : .....

Marital Status : ..... Religion : ..... Occupation : .....

Phone Nos. : ..... Mobile No. : .....

Refd. By Dr. : ..... Under Consultant Dr. .....

2. Diabetic History :

Age of Onset : ..... Mode of Onset : Accidental / Others.....

Duration Of diabetes : ..... Treatment Taken for DM : .....

.....

3. Family History of Diabetes.

Is anybody in the family is suffering from Diabetes : YES / NO
If Yes Father / Mother

PATERNAL					MATERNAL				
GF	GM	UNC	AUN	CS	GF	GM	UNC	AUN	CS

4.A Past Medical History :

	NATURE	SINCE WHEN	MEDICATIONS	PRESENT STATUS
Heart Disease				
Kideny Disease				
Liver Disease				
Asthma / COPD				
Hypertensions				
Chronic Infections				
Others				

ILS/OPD/AAC/2019/21

B. Past History of Hospital Admission / Surgical History :

Reason	Treatment (Surgical / Conservative)	Dates

5. Present History of Diabetics :

A. Present Symptoms : .....

.....

.....

B. Treatment Receiving now :

- ☐ OHA : _____
- ☐ OHA + INSULIN : _____
- ☐ INSULIN : _____
- ☐ ALTERNATIVE MEDICINE : _____
- ☐ NO MEDICINE : _____

C. Any Symptoms Of Hypoglycemia :

If ☐ YES ☐ HOSPITALISATION ☐ DOMESTIC TREATMENT

☐ NO

D. Recent B. Sugar Values.....

Blood Sugar	Values	Date
RBS		
FBS		
PPBS		
HbA1c		
Others		

E. Complication of Diabetes :

	Present / Absent		Duration	Treatment received if any
Eye				
Kideny				
Heart				
Foot				
Nerves				
Others				

6. For Female Patient :

Gravida..... Parity..... H/O GDM.....

Gynecological Problems (If Any) .....

7. Physical Examination :

1. Height : Weight : BMI : EBW :

2. Pulses : Rate : ..... beats per min, Rhythm : Regular / Irregular

- Radial
- Brachial
- Carotid
- Femoral
- Dorsalis Pedis

3. Blood Pressure : Standing : .....mm of Hg; Supine .....mm of Hg

4. Thyroid :

5. Oedema :

6. Respiratory System :

7. Cardio Vascular System :

8. Abdomen :

9. Skin / Eyes :

10. Central Nervous System :

11. Others :

8.Investigation :

Type	Dates										
BLOOD SUGAR											
FBS											
PPBS											
RBS											
Hb1Ac											
RENAL											
Urea											
Creat.											
Micro albumin											
24 Hr. Urine Protein											
Creatinine Clearance											
BLOOD LIPIDS											
Cholestrol											
Triglyceride											
HDL											
LDL											
VLDL											
LFT											
Bill (T)											
Bill (D)											
Bill (I)											
Protien											
Alb											
Glob											
SGOT											
SGPT											
Alk Ph.											
GGT											
Uric Acid											
HAEMOGRAM											
Hb%											
WBC											
DC											
ESR											
Plat.											
PCV											

	Dates										
Albumin											
Glucose											
Ketone											
RBC											
Leukocytes											
T3											
T4											
TS											
Calcium											

TYPES	DATES										
RETINA											
X- RAY											
ECG											
USG											
ECHO											

Foot Examination :

Monofilament :

Right : _____

Left : _____

VPT :

Right : _____

Left : _____

Hot & Cold Perception :

Right : _____

Left : _____

ABI / DOPPLER

Right : _____

Left : _____

DIABETES & OBESITY CLINIC

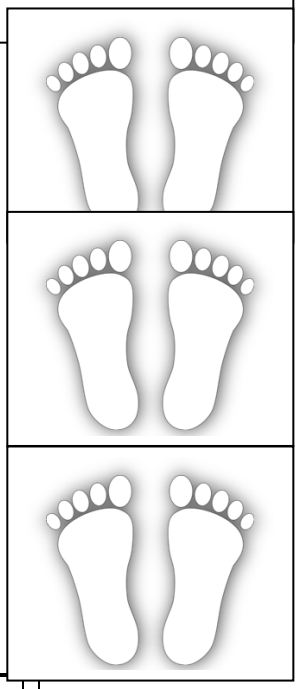
DATE	FOLLOW UP COMPLAINTS	TREATMENT ADVICE

NAME: ……..…… AGE: ……..…..... SEX: ……..…

ADDRESS: ……..……

MOB.NO: ……REFFERING DR.: ……

MEDICAL HISTORY		**DIABETIC FOOT HISTORY**		
			RT	LT
Duration of Diabetes		Duration of Ulcer		
Duration of Hypertention		Past H/O Ulcer		
Hight		H/O Amputation		
Weight		Joint pain		
BMI		Stiffness		
Dyslipidemia		Dry skin		
SMOKER		Numbness		
CVD		Tingling/Pricking		
CKD		Paresthesia		
Blood Sugar		Claudication		
HbA1C		Cramping		
		Oedema		



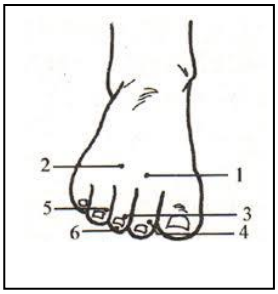
EXAMINATION OF FOOT

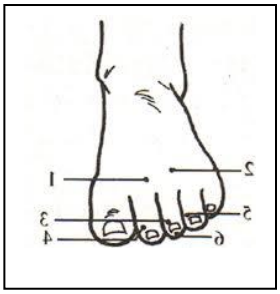
INSPECTION

DRY SKIN	YES	NO	ABNORMAL SHAPE	YES	NO
FISSURE	YES	NO	NAIL LESION	YES	NO
DEFORMITY	YES	NO	LOSS OF HAIR	YES	NO
CALLUS	YES	NO			

PALPATION	HOT	COLD	NORMAL
RIGHT			
LEFT			

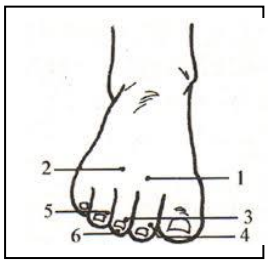
FOOT PULSES	RT	LT
DORSALIS PEDIS		
POTERIOR TIBIALIS		

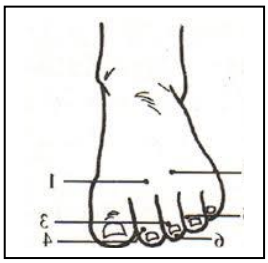




ASSESSMENT OF NEUROPATHY	RIGHT	RIGHT	LEFT	LEFT
MONOFILAMENT				
VPT				
HCP				

VASCULAR ASSESSMENT	RIGHT	LEFT
DORSALIS PEDIS		
POSTERIOR TIBIALIS		
BRACHIALIS		
ABI		





RADIOLOGICAL INVESTIGATION (X RAY FOOT)

RT:-

LT:-

DESCRIPTION OF ULCER

Location :–

Size:-

Base:-

Margins:-

Depth:-

CLINICAL DIAGNOSIS				**WEGNERS CLASSIFICATION**	
	YES	NO		Grade-0	
NEUROPATHY				1-Superficial Ulcer	
CHARCOT FOOT				2-Deep Ulcer	
PVD				3-Osteomyelitis	
INFECTED				4-Localized Gangrene	
OTHERS				5-Extensive Gangrene	

TREATMENT	YES	NO
Callus and Corn Removed		
Nail paring		
I+D done		
Pus for CS		
Probing		
Extensive debridement		
Surgical Referral		
Others		
OFFLOADING TECHNIQUE	YES	NO
S K OFFLOADING		
OFFLOADING SHOE		
TOTAL CONTACT CAST		
INSTANT TCC		
CUSTOM FOOTWEAR		
OTHERS		

FOLLOW UP

Specialised Medical Personnel Curriculum Vitae

Full Name:	DR. GHANASHYAM GOYAL
Academic Title:	SENIOR CONSULTANT - DIABETOLOGIST
Present Position:	PRINCIPAL INVESTIGATOR
Business Address:	ILS Hospltal DD·6, SEC-1 ,SALTLAKE,KOL-64
Relevant Education: (Type of degree and year when awarded)	MBBS-1984, MD-1988
Relevant Previous Positions : (Name of institution and/or organisation and year)	Director & Consultant Diabetologist & Diabetic Foot Specialist, S.K. Diabetes Research and Education Centre,Kolkata - February 2006 - till date Consultant,Dept. of Internal Medicine and Head, Dept. of Dlabetology, ILS Hospital,Kolkata - January 2002 - till date Consultant Physician & Diabetologist - Unit Head, MRS Hospitals - January 1996 - 2002 Consultant Physician & Diabetologist - MRS Hospitals, Kolkata June 1991 - December 1995 Chief Resident - Dept. of Internal Medicine - MRS Hospitals, Kolkata - October 1988 - May 1991
Relevant Job Related Training: (Year of attendance,type of qualification e.g.specialist courses)	Quintiles Online GCP - 2011

Relevant Clinlcal Trial and Research Experience including GCP Training:	PRINCIPAL INVESTIGATOR : A trial comparing the efficacy and safety of insulin degludec I liraglutide and insulin degludec in subject with type 2 diabetes. PRINCIPAL INVESTIGATOR : Efficacy and Safety of H0/03/03 10 ug in the treatment of Neuropathic Diabetic Foot Ulcers - A PHASE II TRIAL (a double blind placebo controlled ,Multicentre study) PRINCIPAL INVESTIGATOR : BIOCHAPERONE PDGF - BB - A phase I/II, multicentre, randomized,controlled, open label trial comparing the efficacy and safety of two dose regimens of BioChaperone POGF - BB to becaplermin gel for the treatment of diabetic foot ulcer. DIABESITY: Role of Insulin Detemir,an open label, observational, multicentric, randomized study in April 2008.
Other Activities Pertinent to Professional Qualifications	**INSUTREAT:** A registry to study the effect of changes of existing Insulin treatment in Inadequately controlled Type 2 diabetes patients till February 2007. The **IMPROVE:** study A multicentre,open label, non randomized, non interventional, observational, safety & effectiveness study in subjects using Biphasic Insulin Aspart 30 for t he treatment of DM in2007.
Certifications and Licensures: (Optional)	Diabetology research course in genetics (Star Steno diabetes educatiori project} at Bangalore inAugJst, 2005. Advanced Diabetes & Endocrinology Preceptorship at John Hopkin's University, School of Medicine, Baltimore, USA in March 2008.

	Faculty & Trainer Staged Diabetes Management for Physicians, conducted by International Diabetes Centre. Started the first Diabetic Foot Clinic of Kolkata & Eastern India in 2003 Regional Coordinator :"National Wound Care Project"(WOF DFSI) Regiona Faculty - Certificate Course in Evidence Based Diabetes Management conducted by Public Health Foundation of India (PHFI) Conducting Workshops on Diabetic Foot all across the country to inc ease awareness amongst Paramedics, Physicians and D1abetologists

Signature of Trial Site Staff/
Specialised Medical Personnel: _____ Date: 07 / Feb / 2022
dd mmm yyyy

NAME: DR REKHA BASAK SRIVASTAVA

E-MAIL ID: ins.rekha2@gma il.com

EDUCATIONAL QUALIFICATION: B Sc, BAMS

Clinical podiatrists and Chief Clinical Research Co ordinator - ILS Hospital, Kolkata

PROFESSIONAL TEAC HING EXPERIENCE TILL DATE:

1. Best paper presentation award in DFSI KOLKATA'2008
2. Master trainer ofIDF Certified course- project HOPE (Indian diabetic educator project)
3. Chief of clinical podiatry program me, conducted workshops at different medical colleges under DFSI wound care project
4. Conducted workshops at different states under Diabetic Foot Education Programme (DFEP).
5. Conducting patient education programme for Diabetes and Diabetic foot every month at ILS HOSPITAL ,SALT LAKE.

Working as Clinical Research Co ordinator :

1. A Phase III, Multicentre, Randomized, Parallel Group, Double Blinded and Control Group Clinical Trial to Assess the Effectiveness of Biochaperone PDGF-BB in the Treatment of Chronic Diabetic Foot Ulcer
2. A trial comparin g the efficacy and safety of insulin degludec I liraglutide and insulin degludec in subject with type 2 diabetes.
3. Efficacy and Safety of H0/03/03 10 ug in the treatment of Neuropathic Diabetic Foot Ulcers - A PHASE II TRIAL (a double blind placebo controlled ,Multicentre study)
4. BIOCHAPERO NE PDGF - BB - A phase I/II, m u lticentre, randomized, controlled , open label
   trial compari ng the efficacy and safety of two dose regimens of BioChaperone PDGF - BB to becaplermin gel for the treatment of diabetic foot u lcer.
5. "Evaluation of Safety and Efficacy of Hydroxychloroquine Sulfate as an Adjunct to Diet
   and exercise to Improve Glycemic Control in Type 2 Diabetes Patients Uncontrolled on Sulfonylurea + etformin Combination" with tudy Code: Ipca/HCQS/PIV-14.
6. Study GOAL: Study of clinical and non clinical predictive factors for achieving glycemic control in people with type 2 diabetes in real clinical practice.
7. Effect and safety of semaglutide 2.4 mg once-weekly in subjects with overweight or obesity and type 2 diabetes.

8. ATOS I A Toujeo ® Observational Study

A 12 month prospective observational study assessing the real world clinical effectiveness , safety and health economic benefits of Toujeo ® initiation after oral antidiabetic drug failure in insulin natve patients with type 2 diabetes mellitus

9. Study Title:A Label extension, Randomized, Double Blind, Placebo Controlled, Multicentre, Single Dose, Phase III Study Assessing the Efficacy and Safety of Peri-ulcer Administration of stempeucel® (Adult Human Bone arrow Derived, Cultured, Pooled, Allogeneic Mesenchymal Stromal Cells) in Patients with Non-Healing Diabetic Foot Ulcer.
10. The clinical trial "An observational, Cross sectional Study to assess the Prevalence of Heart Failure in Type 2 Diabetes Patients in India. Study Code: D1843R00300 "
11. The clinical trial "A Label extension, Randomized, Double Blind, Placebo Controlled , Multicentre , Single Dose, Phase III Study Assessing the Efficacy and Safety of Peri- ulcer Administration of stempeucel® (Adult Human Bone Marrow Derived, Cultured, Pooled, Allogeneic Mesenchymal Stromal Cells) in Patients with Non-Healin g Diabetic Foot Ulcer.
12. The clinical trial "Ref: I8F- MC-GPHK: Efficacy and Safety of Tirzepatide Once Weekly in Participants without Type 2 Diabetes Who Have Obesity or are Overweight with Weight- Related Comorbidities : A Randomized, Double-Blind, Placebo- Controlled Trial(SURMOUNT - 1)"

CAREER HIGHLIGHTS : Clinical Podiatrists since last 15 years.

Trained the paramedics on field of podiatry.

Rekha Basak Srivastava

Dr Rekha Basak Srivastava 16/9/20

NIDA Clinical Trials Network

Certificate of Completion

is hereby granted to

GHANSHYAM GOYAL

to certify your completion of the six-hour required course on:

GOOD CLINICAL PRACTICE

MODULE:	STATUS:
Introduction	N/A
Institutional Review Boards	Passed
Informed Consent	Passed
Confidentiality & Privacy	Passed
Participant Safety & Adverse Events	Passed
Quality Assurance	Passed
The Research Protocol	Passed
Documentation & Record-Keeping	Passed
Research Misconduct	Passed
Roles & Responsibilities	Passed
Recruitment & Retention	Passed
Investigational New Drugs	Passed

Course Completion Date: 13 May 2022

CTN Expiration Date: 13 May 2025

Eve Jelstrom

Eve Jelstrom, Principal Investigator
NDAT CTN Clinical Coordinating Center

Good Clinical Practice, Version 5, effective 03-Mar-2017

This training has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN27201201000024C.

NIDA Clinical Trials Network

Certificate of Completion

is hereby granted to

REKHA BASAK SRIVASTAVA

to certify your completion of the six-hour required course on:

GOOD CLINICAL PRACTICE

MODULE:	STATUS:
Introduction	N/A
Institutional Review Boards	Passed
Informed Consent	Passed
Confidentiality & Privacy	Passed
Participant Safety & Adverse Events	Passed
Quality Assurance	Passed
The Research Protocol	Passed
Documentation & Record-Keeping	Passed
Research Misconduct	Passed
Roles & Responsibilities	Passed
Recruitment & Retention	Passed
Investigational New Drugs	Passed

Course Completion Date: 23 December 2022

CTN Expiration Date: 23 December 2025

Eve Jelstrom

Eve Jelstrom, Principal Investigator
NDAT CTN Clinical Coordinating Center

Good Clinical Practice, Version 5, effective 03-Mar-2017

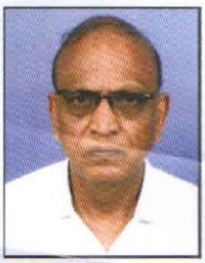
This training has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272012010000024C.

WEST BENGAL MEDICAL COUNCIL

Constituated by the Govt. of West Bengal under Bengal Medical Act, 1914

IB - 196, Sector - III, Salt Lake, Kolkata – 700 106, West Bengal

Updated Registration Certificate - 2022



Registration No.		:	47253 dated 16-06-1989
Name		:	GOYAL DR. GHAN SHYAM
Father's Name		:	SHAREWAN KUMAR GOYAL
Sex		:	MALE
Address :	Permanent	:	IB - 127, SECTOR - III, SALT LAKE CITY, PO : BIDHANNAGAR KOLKATA 700106 WEST BENGAL INDIA
	Present	:	IB - 127, SECTOR - III, SALT LAKE CITY, PO : BIDHANNAGAR KOLKATA 700106 WEST BENGAL INDIA
Qualification :	Basic	:	M B B S (Rajasthan University), 1985
	Additional	:	● M D (Genl. Med.) (Rajasthan University) , 1988 [Regd. on 11-01-2019]

2022

Signature of Applicant Full :

Specimen :

Registrar, WBMC

HOLOGRAM

VALID TILL 31.12.2026