Informed Consent Form

INFORMATION FOR PARTICIPANTS

NAME OF STUDY:	Randomized controlled trial comparing endoscopic balloon dilation versus endoscopic stricturotomy for short strictures (< 3 cm) related to Crohn's disease (the BEST-CD trial)
STUDY NUMBER:	IBD-001
STUDY DOCTOR (INVESTIGATOR):	[Investigator Name]: Dr. Partha Pal Asian Institute of Gastroenterology Pvt Ltd, H. No. 6-3-661, Somajiguda, Hyderabad, Telangana 500082, India Tel No: 040 4244 4222 Mob No: +91 8945906823
ETHICS COMMITTEE	[EC Name]: Institutional Ethics Committee Asian Institute of Gastroenterology, [EC Address]: H. No. 6-3-661, Somajiguda, Hyderabad, Telangana 500082, India [Office Hours Tel]: +91 40 23378888 Extension -802. [Out of Hours Tel]: +91

1)Why are you receiving this information?

You are being asked to consider whether you would like to participate in a clinical research study. A clinical research study is an experimental study of a new therapy, procedure, or drug, and only includes people who want to participate in the study. The following information describes the study and your possible role as a participant. Please read this information carefully and do not hesitate to ask your study doctor any questions to ensure that you are able to make an informed decision as to whether to participate.

2)What is the purpose of this clinical research study?

Crohn's disease is a chronic disease which can involve any part of the intestine from mouth to anus. It usually starts as ulcers in intestinal wall which leads to scarring and narrowing of intestinal lumen. This narrowing in intestinal

lumen can cause symptoms of obstruction like distension of abdomen, pain in abdomen and vomiting. In this study we are comparing two methods of treating such narrowing by non-surgically using endoscopy/colonoscopy (a device with a camera fitted to it which can see the inside of intestine which is introduced through mouth for endoscopy or anus for colonoscopy). The first method is endoscopic balloon dilatation (EBD) in which a balloon introduced into the intestine through a endoscopy/colonoscopy is inflated inside the stricture so that it opens up. The second one is known as endoscopic stricturotomy (EST) (stricture means narrowing, tomy- means cutting) in which the stricture is cut with the help of endoscopic knife introduced through endoscope or colonoscopy. The purpose of the study is to compare the safety and efficacy of EST versus conventional EBD in the treatment of stricture in Crohn's patients.

3)Approximate Number of Participants and the Expected Duration of Your Participation in the study.

Patients- 100
Duration- during the procedure and until discharge. However further follow up is optional at 3 and 6 months by physical visit or telephonic communication. followup may be up to 6 months based on condition

4) Study procedures:

If Crohn's disease involving stricture based on your symptoms (e.g., abdominal pain, loose stools, weight loss, fever, or any other complaints) and/or based on previous CT/MRI scans and your clinician thinks that you need an endoscopic examination of stricture, you will be advised to undergo either Endoscopic balloon dilatation (EBD) or endoscopic stricturotomy (EST) directed earlier. The decision to undergo the type of endoscopy procedure either EBD or EST would be decided based computer based 1:1 random distribution. For such investigation, you will be kept on fasting for minimum 8 hours and will be given 4 liters of medicated solution to clear your small intestine from stool to enable small bowel visualization. For both procedures, you will undergo check up for the fitness to undergo the same in the form of ECG, Chest X ray, blood investigations as suggested by the treating or anaesthesia doctors. Proper observation and precaution would be taken as per institutional protocol for anaesthesia. While you're under anesthesia, the anesthesiologist monitors your body's vital functions and manages your breathing usually with the help of ventilator machine through a tube inserted through the nose. Usually after the procedure you will be discharged the next day unless your medical condition warrants further hospital stay.

5)Adverse reactions :
This study is comparing two standards of Treatment. This procedure may have few side effects. The minor adverse reactions would be pain, minor bleeding which stops spontaneously and dysfunction during procedure not leading to prolongation of hospital admission. These can occur in 1 in 10 patients. Major side effects include prolonged hospital admission due to pain or any other cause like bleeding requiring adding of metal clips, blood transfusions, perforation (leak in the intestine). Major side effects are rare and can occur in 1 in 100 patients. You will be provided standard of care for the same by the hospital as the standard of care as both procedures are well accepted techniques for stricture management in Crohn's disease. General anesthesia/sedation are overall very safe; most people, even those with significant health conditions, are able to undergo general anesthesia/sedation itself without serious problems.In fact, your risk of complications is more closely related to the your general physical health, rather than to the type of anesthesia. Older adults, or those with serious medical problems, may be at increased risk of postoperative confusion, pneumonia, or even stroke and heart attack. We are excluding all these patients at the onset

from our study.

6) Benefits and disadvantages :

As balloon is associated with higher risk of perforation and lower risk of bleeding and knife associated with higher risk of bleeding and lower risk of perforation.You will be experiencing the treatment that may be more effective than the standard approach. You will have an active role in your own health care and gain a greater understanding of your disease or condition. Even if you don't directly benefit from the results of the clinical trial you take part in, the information gathered can help others and adds to scientific knowledge.You will also not suffer any disadvantage from participating in this study, except that it my take your additional time.

7) Voluntary Participation / Withdrawal from the Study

Your participation in this study is entirely voluntary. It is up to you to decide whether to take part or not. Even if you do decide to take part, you are free to leave the study at any time without giving a reason. This will not affect your future medical care in any way. Furthermore, your study doctor may withdraw you from the study if he/she feels this is in your best interest, or in case of stopping the study early. If you decide to withdraw your consent to participate in the study, your study doctor will ask your agreement to perform the final evaluation and to collect the data through a report form. If you do not agree, no new data on you will be added to the database.

Your doctor, the Sponsor of the study or design may end your participation in this study at any time without your consent. Possible reasons for ending your participation are if the study treatment offers you little or no future benefits or if you develop severe or life-threatening side effects. You will be discontinued from the study if you fail to follow directions for participating in the study.

8) Permission for Review of Records, Confidentiality and Access to Records

The study doctor or research staff will collect information about you. This information called data, will be entered without your name, on a report form. In all of these report forms a code will replace your name. All the data collected will be kept confidential.

The data collected will be used for the evaluation of the study, and may be used in the future in related or other studies. The data may be submitted to health authorities for registration purposes, Member of the health authorities, ICMR and like Institutional Ethics Committee (IEC) / Institutional Review Board (IRB) or other persons required by law may review the data provided. This data may also be used for the purpose of publication.

In order to make sure that the data collected from you is correct. It is necessary for the sponsor or national / International authorities to directly compare them with your medical record. Such checks will only be done by qualified and authorized personnel. While all reasonable efforts will be made to keep the data confidential, absolute confidentiality cannot be guaranteed.

If you agree, your personal doctor will be informed of your participation in the study.

9) Questions/Information

If you or your representative(s) have any questions regarding the study or in case of study related injuries, you should contact your study doctor at this telephone no. +91 040 4244 4222

- If you or your representative(s) have any questions regarding your patient rights as they relate to the study, you should contact the following personnel as allowed by local regulation and IRB/IEC policy,
- If you seek emergency care, or if hospitalization is required, please inform the treating doctor that you are participating in this clinical study.
- If any new information becomes available during the course of the study that may affect your willingness to participate, you will be informed.

10) Use and storage of your data

Your medical data and personal data are collected and used for this research. This concerns your age, gender, the type of work and / or study you are doing, your length of illness and any operations and / or medication that you (have) used. Each participant will receive a code that will appear on the data. Your name will then no longer be used**.**

11) Your data

This is an anonymous. All your details remain confidential. Only the researcher knows which code you have. The research data cannot be traced back to you when published in a (scientific) journal.

If you sign the consent form, you consent to the collection, storage and viewing of your medical and personal data. The researcher will keep your data for 15 years. The personal data is then destroyed.

6. Compensation for participating

You will not receive any expenses for participating in this study.

Contact Information

If you have questions or would like more information about this study contact:

Study Coordinator Kanneganti. Swathi

If you are injured or hospitalized for any reason during the study, contact

Study Doctor or Principal Investigator DR.PARTHA PAL

Mobile No: +91 8945906823

If you have questions about your rights as a study subject, contact:

Institutional Ethic Committee (EC) Dr. S. Isaac Raj

Mobile No: +91 9652588075

11) Consent Signatures

Please read this section carefully and if in agreement please sign and date at the bottom of the page:

- I have been provided the details of the known or foreseeable side effects and risks of the research medication and study procedures that I may receive.
- I understand I am free to accept or refuse my participation at any time without giving a reason. My decision to accept or refuse my participation will have no effect on my continuing treatment. I understand that I am free to discontinue my participation at any time without giving a reason. My decision to discontinue my participation will have no effect on my continuing in treatment. I will keep all my rights to treatment and alternative therapy.
- I agree that data collected for the study will be used for the purpose described above, including transferring data to the case report form or data base and processing and archiving by AIG in a coded form with respect to confidentiality of my data.
- I agree that direct access to my medical records may be given to authorized persons representing as well as national and international authorities. These authorities may include the regional regulatory authorities or Institutional Ethics Committee (IEC)/Institutional Review Boards (IRB).
- I understand that my study records can be forwarded to my primary physician if I request my study doctor to do so.
- I will not lose any rights that I have under law by signing and dating this form.
- I have read and understand the information presented in this informed Consent Form. I have been given the opportunity to ask questions have been answered.
- I will receive a signed and dated copy of this Informed Consent Form.

12) Signature:

I freely accept to participate in this study

Please initial box
(Subject/ Patient)

(i)	I confirm that I have read and understood the information mentioned in this Informed Consent Form dated ----------(DATE) for the above study and have had the opportunity to ask questions. I have been informed of the nature, purpose procedures, duration and foreseeable effects and risk of the study, of its possible advantages and inconveniences and what I will be expected to do. I also understand that I may not benefit at all from this treatment offered to me. My questions have been answered satisfactorily.	[ ]
(ii)	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[ ]
(iii)	I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	[ ]
(iv)	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)	[ ]
(v)	I agree to take part in the above study. I agree to co-operate and inform unexpected or unusual symptoms experienced during the study. For the duration of the study, I will notify the investigator of any other medical treatments that may be necessary to undergo.	[ ]

To be signed simultaneously, (i.e. same date), by all parties:

_____	_____	_____
Print Name of < Subject / Patient >	Date (to be entered by Subject)	Signature / Thumb Impression

(When consent of the subject/patient cannot be obtained the following signature should be added*:)*

Name of <subject's/patient's> legally acceptable representative		
_____	_____	_____
State relationship to the subject	Date (to be entered by legally acceptable representative)	Signature / Thumb Impression

I have explained the study protocol and research involved, to the subject and answered all of his/her questions. I believe that he/she understands information described in this document and freely gives permission for his/her to participate.

_____	_____	_____
Name of Study Investigator or (Designee) obtaining consent	Date	Signature

(If the subject/patient / legally acceptable representative cannot read:

_____	_____	_____
Name of Impartial Witness 1	Date (to be entered by witness)	Signature
_____	_____	_____
Name of Impartial Witness 2	Date (to be entered by witness)	Signature

Distribution: original for study doctor, copy to Subject/ Patient