



Written Informed Consent Form for Enrollment into PSBI Study 1

This consent form will be administered to the parent/ accompanying guardian of a young infant (i.e. aged 0-59 days) after the hospital physician/nurse have completed screening and found the young infant to be eligible for enrollment into Study 1, based on pre-specified inclusion and exclusion criteria laid out in the study protocol.

Study Title: Optimizing place of treatment and antibiotic regimens for young infants presenting with any single low-risk sign of clinical severe infection

Overall Principal Investigator (UP): Dr. Vishwajeet Kumar, Community Empowerment Lab (CEL)

Site Principal Investigator: Prof (Dr) Yashwant Kumar Rao, Head of the Pediatrics Department, GSVM Medical College, Kanpur

Organization: GSVM Medical College, Kanpur

Version Date: 06 April 2020

Part I: Invitation for Participation

Namaskar! My name is _____, and I represent the GSVM Medical College, Kanpur and Community Empowerment Lab (CEL), Lucknow. We are supporting the government and medical and scientific communities in developing evidence-based solutions to improve the health of children. We are conducting a research study in collaboration with the World Health Organization (WHO) and National Health Mission, Uttar Pradesh (NHM-UP) in Kanpur Nagar district. This research study is implemented such that some infants aged < 2 months presenting with less severe signs of clinical infection are admitted to the hospital and receive inpatient treatment, while others are receiving outpatient treatment at home. The purpose of this study is to find out which of these two approaches is better. I am working as a study team member associated with this research study. Your infant has been screened to be eligible to participate in this study and I would like to give you complete information about this study, and seek your consent to allow your child to participate in it.

Before you decide, you can talk to anyone you feel comfortable with. If there is any information that you do not understand well, please tell me and I will take time to explain in detail. If you have questions later at any time during the course of treatment and follow-up, you can ask them of the treating physician/nurse, study staff or me.

Purpose of the Study

It is currently recommended that all infants less than 2 months of age with clinical severe infection should be treated in the hospital. The treatment usually includes injectable antibiotics for 7-10 days. However, it has been observed that infants who have only one of these signs – fast breathing (only in infants 0-6 days of age) or fever (body temperature $\geq 38^{\circ}\text{C}$) or severe chest indrawing – have rare treatment failure, irrespective of the place of treatment. Therefore, while the current guideline in such a case is to admit and treat the child in the hospital, we find that treating the child at home while continuing to monitor them may not pose significant additional risk to the infant. We are doing this study to compare and find which of these 2 options is better. If we find that home treatment is safer than hospital treatment, we will update the clinical guideline for all such cases.

Procedure

As I mentioned, there are two possible ways of treating your child:

- **Treatment Plan 1:** Hospital admission with two injectable antibiotics - one injection (called ampicillin) will be given four times a day and the other injection (called gentamicin) will be given once daily, for 7 days. This is the current global guideline for treating such cases, and is the standard way that infants with your child's conditions are treated.
- **Treatment Plan 2:** Home treatment with two antibiotics- one injectable antibiotic (called gentamicin) will be given once daily for the first two days and an oral antibiotic (called amoxicillin) will be given twice daily for 7 days. We have observed this treatment in special circumstances, and found that it does not pose significant additional risk to babies, provided that they are monitored regularly. We have taken special permission to test and compare this treatment plan against the standard Treatment plan 1.

If you agree for your baby to participate in this study, then

- A sealed envelope will be opened in front of you. A paper inside the sealed envelope will have either 'Treatment Plan 1' or 'Treatment Plan 2' written on it. No one in my team knows what is written on paper inside the envelope. This is somewhat like a lottery – we want to do this to ensure that this process is fair. By agreeing to participate, you are agreeing to accept and follow the treatment option written inside the sealed envelope for your baby – regardless of whether it is #1 or #2. We will not be able to change the treatment option after the envelope is opened. So please consider this very carefully before agreeing to consent.
- If assigned to Treatment Plan 1, i.e., standard hospital treatment, your child will be admitted to this hospital, and will receive two types of injectable antibiotics for 7 days. This is our normal procedure and the entire treatment (admission charges, medicines, and consumables) is free of cost. Even if you choose to not participate in this study, this is the treatment that your child will receive, as it is currently the standard treatment.
- If assigned to Treatment Plan 2, i.e., home treatment, your child will be given one injection (called gentamicin) along with the first dose of oral antibiotic (called amoxicillin) now. Then, your child will be sent home with you. You will need to administer the oral antibiotic yourself twice daily (that is every 12 hours) to your child for 7 days. You will be asked to return to the hospital for the second dose of the injection and check-up by the hospital physician/nurse tomorrow and only for check-up on Day 4 – we will arrange for the transportation. If you are unable to come to the hospital due to any reason, then you can also visit the nearby health facility or ANM for the second injection and check-up. We will teach you how to administer the oral antibiotic and monitor the baby yourself at home.
- During the treatment, if anytime you feel that your child's condition is not well (such as appearance of fever, chest in-drawing, fast breathing, poor feeding, reduced movement or hypothermia). Or they develop any danger signs (such as not feeding at all or no movement at all or convulsions) about which you will be advised, please immediately bring your child back to this hospital or ask study physician/nurse. They will provide prompt treatment and support to child.
- A study staff will record the treatment given to your child on days 1, 2, and 4 of treatment. A study staff will visit you in the hospital or home to find out how your baby is doing on day 8 after initiation of treatment.
- Another study staff will visit your child (either in the hospital or at home) on day 2, 4, 8 and day 15 of treatment. The study staff will ask you questions about how child is doing and assess them



in detail. The study staff will record a video or make a video call to a supervising clinician to cross-verify the assessment findings. The supervising clinician will see your child on the video call which will help in ascertaining the assessment findings. This video call will not be recorded. If you do not want your child to participate in video call, you can let us know.

Voluntary Participation

Your participation in this research is completely voluntary. You have the right to choose whether or not to allow your child to participate in this study. You can also withdraw your child from the study any time even after you have agreed for it. However, we would request you to please ask us for any clarifications and consider all the aspects into your decision-making before consenting, to the extent possible. A copy of this informed consent form will be provided to you. You will not have to pay any payment or penalty for not participating in this study. If you choose not to participate in this study, you will receive the standard treatment from hospital and your medical care or rights will not be affected in any way.

Confidentiality

Any information collected from this study will be used solely for this research study. Only authorized research staff members will have access to documents and data related to the research. If you consent for the video/ video call, it will be stored securely for quality purposes, and will never be shared with anyone other than the supervising clinician and the principal investigator/ co-principal investigator. We may publish a summary of findings from this research study but we will not publish any information that may identify you. All the information shared by you during this study will be kept strictly confidential and will be stored securely and anonymously on a digital platform.

Risks and Discomforts

Your infant has presented with signs of clinical severe infection. This illness carries a risk of adverse consequences if not identified and treated in a timely manner. Since your infant has been identified with a low risk sign, they have a good chance of improvement if they receive their prescribed treatment.

The medicines being used in this study are used in young infants throughout the world and are generally known to be safe, but they can rarely cause diarrhea, stomach ache or a skin rash. If you see your child has skin rash, diarrhea, or any other problem irrespective of the treatment plan, please let us know immediately and we will revise the treatment plan, if needed. Contact the study staff or the person listed below if you have any questions about the drugs. As mentioned, all information, videos, etc., will be kept strictly confidential.

It has been observed that the outpatient treatment for infants with only one low risk sign of clinical severe infection does not pose any significant additional risk to babies as compared to inpatient care in the hospital if they are provided the prescribed treatment and monitored regularly. If your child is assigned Treatment Plan 2 and in the rare case of the child's condition deteriorating at home, you should immediately call us on the number provided on the child's treatment card. **We will arrange to bring the child back to the hospital immediately and provide them prompt treatment and support.** We will provide you detailed counseling on administering oral antibiotics at home and recognizing danger signs, so you may recognize these in time and seek prompt care. Infants assigned to Treatment Plan 1 will be monitored on a daily basis by our team of doctors and nurses, but we still advise you to be observant and let us know



if you observe any deterioration in the child's condition while admitted in the hospital, and we will immediately provide the necessary care and support.

Benefits/incentive for the participation

There is no financial or other in-kind incentive to participate in this study. Treatment for the infant will be free of cost, regardless of whether or not you consent to participate in the study. There may not be a direct benefit for your child at this stage, but their participation will bring benefit for improving care of infants in the near future. If the finding of this study shows benefits of Treatment Plan 2 (home treatment) over Treatment Plan 1 (standard hospital treatment), you will have contributed to change global recommendations on care for all young infants with a single low-risk sign of clinical severe infection.

Whom do I call if I have questions or problems?

This study has been reviewed and approved by the members of an ethical committee. The task of this committee is to make sure that research participants are protected from harm. If you have any questions about the study, please contact

Dr. Yashwant Rao

Site PI/ Head of Department, Pediatrics
GSVM Medical College,
Kanpur – 208002, Uttar Pradesh
Phone – +91-9415080807
Email id: ykraoneo@yahoo.co.in

Dr. Vishwajeet Kumar

Principal Investigator
Community Empowerment Lab
26/11 Wazir Hasan Road
Lucknow – 226001, Uttar Pradesh
Phone – 0522-4973444
Email id: vkumar@celworld.org

If you have any questions or concerns about the ethical conduct of the trial, you may contact the Ethics Committee of the study.

Ethics Committee GSVM medical College,

Opp. CRS Complex, GSVM Medical College, Kanpur – 208002, Uttar Pradesh
Phone – +91-9454581649
Email id: ec.gsvmmedicalcollege@gmail.com



Part II: Certificate of Consent

A. Parent/ guardian of child:

I confirm that I have read/heard this consent form and understood the purpose, procedures, possible benefits and risks of this research study. I have had the opportunity to ask questions and have got satisfactory answers to all my questions and queries.

- I understand that by consenting to participate in this study, I accept that my infant may be assigned to either hospital or home-based treatment based on a sealed envelope, and I agree to follow the assigned treatment plan.
- I am aware that if I choose not to participate in this study, my infant will be admitted and provided standard care in the hospital.
- I understand that my participation is completely voluntary and I am free to withdraw my child from this study at any time without giving any reason and without my medical care or rights being affected.
- I have agreed to cooperate/contact with the nurse/physician and the research staff and inform them or contact immediately if my child experiences any unexpected or unusual symptoms.
- I am aware that I will be given a copy of this consent form for my own records.
- My child's participation in this study will be kept strictly confidential.
- I don't need to pay and neither will I receive any payment or incentive for my child's participation in this study

I voluntarily agree to enroll my child in this study.

Yes

☐

No

☐

Name and Signature/Thumb impression of participant

Date (dd/mmm/yyyy)

B. Witness to the Consent (if parent is illiterate):

[If the mother/father is illiterate and is not able to sign her/his name, a literate witness other than the member of the study team needs to sign that they confirm that the participant has agreed to allow her/his child to be the part of the study.]

I have witnessed the accurate reading of the consent form to the mother/father of the child, who has had the opportunity to ask questions. I confirm that the parent has given his/her consent freely.

Name of Witness to the Consent

Signature

Date (dd/mmm/yyyy)

C. Study Team Member Obtaining Consent

I have accurately read the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm the consent was given freely.

Name of Research Team Member

Signature

Date (dd/mmm/yyyy)