OR GANIZATION: BAHAWAL VICTORIA
PRINCIPLA INVESTIGATOR: MUHAMMAD ALI FAYYAZ
SUB-INVESTIGATORS: MUHAMMAD ANEES UR REHMAN
MUEEZ HAIDER

Informed Consent Form

Different Approaches of Spinal Anesthesia in Patients Undergoing Cesarean Section

NCT Number: NCT05637645

11/6/2022

Informed Consent

Bahawal Victoria Hospital/ BM&D Hospital/ Hameed Latif Hospital/ Laeeque Rafiq hospital

Informed Consent form for patient.

This Informed Consent Form is for pregnant women who attend Bahawal Victoria Hospital/ BM&D Hospital/ Hameed Latif Hospital or Laeeque Rafiq Hospital, and who we areinviting to participate in research.
The title of our research project is: Different Approaches of Spinal Anesthesia in Patients Undergoing Cesarean Section

Name of Principal Investigator: Dr Muhammad Ali Fayyaz
Name of Organization: Bahawal Victoria

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

I am Dr. Muhammad Ali Fayyaz, working in BM&D Hospital. We, Dr Anees ur Rehman and Dr. Mueez Haider along with Dr. Muhammad Ali Fayyaz, are doing research on different approaches of spinal anesthesia. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide,you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.)

Purpose of the research

Spinal Anesthesia through lumbar puncture is a common procedure being used in pregnant females before Cesarean surgery. Different approaches of spinal anesthesia have been identified; Midline, Paramedian and Taylors approach. The reason we are doing this research is to compare the effects of different approaches with respect to common complications and vitals monitoring.

Type of Research Intervention

This research will involve a spinal anesthesia through lumber puncture by spinal needle. However, local anesthesia may be used if required before lumber puncture.

Participant selection

We are inviting all pregnant females who attend Bahawal Victoria Hospital, Bahwalpur/ Bahawalpur Medical & Dental Hospital, Bahwalpur/ Hameed Latif Hospital, Lahore/ Laeeq Rafiq Hospital, Multan to participate in the research.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at the hospital will continue and nothing will change. If you choose not to participate in this research project, you will offer the treatment that is routinely offered in this hospital and we'll tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

Procedures and Protocol

In first times, participants in 1st group will be given spinal anesthesia through midline approach while participants in the 2nd group will be given spinal anesthesia through paramedian approach and participants in the 3rd group will be given spinal anesthesia through taylors approach.

This is the best way we have for testing without being influenced by what we think or hope might happen. We will then compare which of the three has the best results.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the approach of procedure is doing, we will find out which approach you are getting and make changes. If there is anything you are concerned about or that is bothering you about the research please talk to me or one of the other researchers.

B. Description of the Process

- In the first time, spinal anesthesia will be given to you through lumbar puncture by spinal needle after asking few questions pre-operatively which will be asked one by one.
- We will also ask you a few questions about your general health and measure how tall you are and how much you weigh.

Duration

The research takes place over 3-4 days or may be a week.

Risks

Any risk can appear during the process. The healthcare workers will be looking after you and the other participants very carefully during the study.

Benefits

If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. There may not be any benefit for you but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

Reimbursements

Your participation is free but you will be charged for cesarean surgery. You will not be given any other money or gifts to take part in this research

Confidentiality

With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone.

Sharing the Results

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Alternatives to Participating

If you do not wish to take part in the research, you will be provided with the established standard treatment available at the hospital.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [Dr Muhammad Ali Fayyaz, Dr Anees ur Rehman and Dr. Mueez Haider]

This proposal has been reviewed and approved by [Department of Medical Education Bahawal Victoria Hospital Bahwalpur], which is a committee whose task is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [Dr. Sophia Farukh, Quaid e azam Medical college/ Bahawal Victoria Hospital, (062) 2731042]). It has also been reviewed by the Ethics Review Committee of the hospital who is supporting the study.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date_____

Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND Thumb print of participant**

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.
2.
3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date_____
Day/month/year