

ADULT STUDY INFORMATION AND INFORMED CONSENT FORM FOR PREGNANT PARTNERS OF STUDY PARTICIPANTS

Study Code:	D702NC00001	Centre No:	3514
Sponsor:	AstraZeneca AB	Subject E Code:	
Principal Investigator:	Dr. Prashant Pandey		
Study Title:	Phase III, Randomized, Open-label, Global, Multicenter Study of Rilvegostomig or Durvalumab in Combination With Chemotherapy as a First-line Treatment for Patients With Advanced Biliary Tract Cancer (ARTEMIDE-Biliary02)		
Country:	INDIA		

You are being asked for information about yourself and your pregnancy because you have become pregnant while your partner was taking part in the research study D702NC0001 ARTEMIDE-Biliary02. Whether you share this information or not is completely up to you. Take the time you need to read this form and ask the study doctor any questions. You can talk to your family, friends or family doctor before you decide. If you decide to let us have your information, you must sign this form, to show that you agree to allow us to use your personal information.

WHY ARE WE DOING THE RESEARCH STUDY YOUR PARTNER IS TAKING PART IN?

Your partner agreed to take part in the research study because he has biliary tract cancer. The reason for the study is to find more effective treatment for biliary tract cancer.

AstraZeneca is doing this research to find out if the experimental medication called rilvegostomig together with chemotherapy (cisplatin and gemcitabine) will work and be safe for the treatment of biliary tract cancer]. Rilvegostomig is not approved by any health authority, except for use in research studies like this. The hospital / clinic / doctor is being paid by AstraZeneca to do the research. AstraZeneca AB, 151 85 Södertälje,

Sweden is responsible for your personal information and any results from research described in this document is owned by AstraZeneca AB, 151 85 Södertälje, Sweden.

WHY ARE WE ASKING YOU FOR INFORMATION ABOUT YOU AND YOUR PREGNANCY?

Not all risks and side effects are known for rilvegostomig. We do not know if rilvegostomig can pass from the bloodstream into semen or whether it has any effects on sperm, pregnancy, or a baby before or after birth. We would like to collect information about you and your pregnancy, to see whether anything happens that might be related to rilvegostomig.

DO I HAVE TO GIVE THIS INFORMATION AND CAN I CHANGE MY MIND?

It is entirely up to you whether you give us information about your pregnancy or not.

You can decide to stop giving us information about your pregnancy at any time, but you have to tell the study doctor. You do not have to explain your reasons for stopping, but it would be helpful for us to know. If you stop, you may still contact the study doctor if you want to get information about rilvegostomig.

WHAT DO I HAVE TO DO?

If you agree, we will contact you after you have given birth to your baby. We will ask you about your pregnancy and delivery and the health of your baby. Also, please contact the study doctor if you have a miscarriage or if you decide to have an abortion.

We will collect the following information from you:

- Relevant medical history
- Details of any previous pregnancies, including outcome and any complications
- Details about this pregnancy
- Any drugs that you are taking during this pregnancy
- The outcome of this pregnancy
- Details about the birth and your baby

The study doctor will not examine you or do any tests. You will only be asked to answer questions and provide information.

You will not be paid for giving us this information. We will not cover any costs related to your pregnancy, delivery or care of your baby or any miscarriages or abortions. The

information about your pregnancy may help us understand how the rilvegostomig affects pregnancies.

WHAT IF NEW INFORMATION BECOMES AVAILABLE?

We will tell you if we get any new information on the effects of rilvegostomig on pregnancy.

HOW WILL MY PERSONAL INFORMATION BE HANDLED AND USED?

To get the answers we need, we have to collect personal information about you and your pregnancy. This includes the answers to our questions about your pregnancy and previous pregnancies. We will do everything we can to make sure that no one, except the study doctor/hospital/clinic and study inspectors, know who you are. We do this by using a code instead of your name and only these people will have the key to the code. Both the study doctor/hospital/clinic and AstraZeneca will make sure your personal information is protected. Health authorities and people helping AstraZeneca to run the study, including members of the AstraZeneca group of companies, contractors, sub-contractors and any company that AstraZeneca goes into business with, or sells all or part of its business to, will be allowed to see your personal information but they will not know who you are unless they are study inspectors.

The study site and the sponsor are obliged to keep all personal information from this study for 25 years after the end of the study, unless there is a legal requirement for keeping them longer. At the end of this retention period your coded data will be deleted or anonymised.

You can find out more about how AstraZeneca group of companies keeps personal information at www.astrazenecapersonaldataretention.com. Results will be used to learn about rilvegostomig and for application for rilvegostomig to be approved for prescription to patients. It may also be used to answer other questions including safety of rilvegostomig.

Results from this study will be published for example in medical journals or online, but you will not be mentioned in a way that would let people find out who you are. Researchers from for example AstraZeneca, other health related companies, and universities might ask to use information from this study, including your information for other medical and healthcare related research. The researchers may combine the results from this study with results from other studies. AstraZeneca will look at what they want to do before they share it. If sponsor shares your information AstraZeneca will make sure that they cannot find out who you are.

Your personal information will be sent to another country(ies) , to combine it with the information collected in the study, or for other reasons such as long-term storage. When we send your personal information to another country, the way we do it is either controlled by a contract approved by Sponsor's own privacy rules which have been approved by privacy authorities (called Binding Corporate Rules). Your personal information will still be kept completely private, no matter which country it goes to, even if that country does not have such strict data protection laws as India .

You can ask your study doctor to see the information that has been collected about you. If you think any of it is wrong, you can ask the study doctor in writing if it can be changed or removed. You can also ask that we restrict the use of your personal information. If you change your mind about providing information regarding yourself and your pregnancy, we cannot remove the personal information that was collected for this research study before you stopped.

If you have questions about how we use your personal information or want a copy of the Binding Corporate Rules, please ask the study doctor first. You may also ask the Sponsor Data Protection Officer at privacy@astrazeneca.com or at the Global Data Protection Officer, 1 Francis Crick Avenue Cambridge Biomedical Campus CB2 0AA Cambridge, UK. If you are not happy with the answers you get, you can complain to Drugs Controller General (India).

WHOM SHOULD I CONTACT IF I NEED MORE INFORMATION OR HELP?

Institutional Ethics Committee_ has reviewed the plans for the study including this form.

If you have any questions about the research study, you can contact:

Principal Investigator:	Dr. Prashant Pandey
Phone No:	+91-9804290687
Email:	prashantpandeydr@gmail.com
Sub-Investigator/Study Coordinator:	
Phone No:	

Hospital name and Address:	Tata Medical Center 14 MAR(E-W), Newtown, Rajarhat, Kolkata-700160
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If you have questions about your rights or research study, you may contact:

Name of Ethics Committee	Institutional Review Board
Name of Ethics Committee's Member Secretary/Chairperson <i>(Member Secretary or Chairperson as applicable per EC SOP)</i>	Dr. Indranil Mallick (Member Secretary)
Phone No:	+91-9831171235

Trial Result Summaries are a short and easy to understand summary of the results of this study. These will be added to www.trialssummaries.com within 1 year of the last study participants last site visit. You can visit www.trialssummaries.com website anytime to sign up to be notified via email when the trial results summary of this study is available.

Trial Result Summaries will also be posted on <http://euclinicaltrials.eu>.

A description of this clinical trial will also be available on <http://www.clinicaltrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Information in technical language related to study protocol and the results will be posted on <http://astrazenecaclinicaltrials.com> and <https://www.clinicaltrialsregister.eu/> and euclinicaltrials.eu. A description of this study is also available on <http://ctri.nic.in>. These websites do not contain any information about you.

INFORMED CONSENT FORM

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By signing this form, you confirm the following:

- I have had time to read and think about this information and my questions have been answered properly.
- I agree to give personal information about myself, my pregnancy, and my baby.
- I have been informed on the way my coded personal information may be collected, used and shared as described in this document.
- I agree that my coded personal data can be used for other medical, healthcare or scientific related research purposes Yes ☐ No ☐

*Signature (Or Thumb impression) of the Pregnant Partner
of Study Subject/Legally Acceptable Representative (LAR)*

Date of Signature

Signatory's Name (Name of the Pregnant Partner of Study Subject or LAR who has signed)

Where a pregnant partner of study subject is not able to give informed consent (e.g. an unconscious person or those suffering from severe mental illness or disability), the same may be obtained from a legally acceptable representative (a legally acceptable representative is a person who is able to give consent for the pregnant partner of study subject as provided by the law(s) of India).

Relationship of legally acceptable representative to pregnant partner of study subject

Signature of the Investigator

Date of Signature

Study Investigator's Name

Signature of Impartial Witness

Date of Signature

Name of Impartial Witness

Copy of the Patient Information Sheet (Pregnant Partners of Study Participants Information) and duly filled Informed Consent Form shall be handed over to the pregnant partner of study subject or her legally acceptable representative.