

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 as you have got pregnant while your partner was participating in the research study D702NC00001 ARTEMIDE-Biliary02. Whether or not you share this information is totally up to you. Take the time you require to read this form and ask the study doctor any queries. You may speak about it with your family, friends or family doctor before you make a decision. If you choose to let us have your information, you should put a signature on this form, to indicate that you agree to permit us to use your personal information.

WHY ARE WE CONDUCTING THIS RESEARCH STUDY YOUR PARTNER IS PARTICIPATING IN?

Your partner consented to participate in the research study as he is having biliary tract cancer. The purpose of this study is to find more effective treatment for biliary tract cancer.

This research is being conducted by AstraZeneca to find out whether the experimental drug known as rilvegostomig along with chemotherapy (cisplatin and gemcitabine) will work and be safe for treating biliary tract cancer. Any health authority have not approved Rilvegostomig, except for use in research studies such as this. AstraZeneca is paying the hospital / clinic / doctor to do the research.

AstraZeneca AB, 151 85 Södertälje, Sweden is responsible for your personal information and AstraZeneca AB, 151 85 Södertälje, Sweden is the owner of any results from research explained in this document.

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

All risks and side effects are not known for rilvegostomig. We are not aware whether rilvegostomig may pass from the bloodstream into semen or if it has any effects on sperm, pregnancy, or a baby before or after birth. We wish to gather information about you and your pregnancy, to find out if anything occurs that may be associated with rilvegostomig.

DO I NEED TO PROVIDE THIS INFORMATION AND CAN I CHANGE MY MIND?

It is totally up to you whether or not you provide us information about your pregnancy.

You may choose to stop providing us information about your pregnancy at any time, but you will have to inform the study doctor. You do not need to give an explanation of your reasons for stopping the participation, but it would be helpful for us to understand it. If you stop, you can still get in touch with the study doctor if you would like to receive information about rilvegostomig.

WHAT DO I NEED TO DO?

If you consent, we will get in touch with you after you have given birth to your baby. We will ask you regarding your pregnancy and delivery and your baby's health. Also, kindly get in touch with the study doctor if you are having a miscarriage or if you choose to have an abortion.

The following information will be collected from you by us:

- Relevant medical history
- Details of any earlier pregnancies, which includes outcome and any complications
- Details regarding this pregnancy
- Any medications that you are consuming during this pregnancy
- The result of this pregnancy
- Details regarding the birth and your baby

The study doctor will not check you or perform any tests. You will only be asked to respond to queries and give information.

Payment will not be given to you for giving us this information. Any costs associated with your pregnancy, delivery or care of your baby or any miscarriages or abortions will not be covered by us. The information regarding your pregnancy can help us know about how the pregnancies are affected by rilvegostomig.

WHAT WILL OCCUR IF NEW INFORMATION BECOMES AVAILABLE?

You will be informed by us if we get any new information about the effects of rilvegostomig on pregnancy.

HOW WILL MY PERSONAL INFORMATION BE HANDLED AND USED?

To receive the answers we require, we will need to gather personal information about you and your pregnancy. The answers to our queries about your pregnancy and earlier pregnancies will be included in this. We will do everything we can to ensure that nobody, except the study doctor/hospital/clinic and study inspectors, know who you are. We will do this by using a code in place of your name and these people will only have the key to this code. The study doctor/hospital/clinic and AstraZeneca will both ensure your personal information is safeguarded. Health authorities and people that help AstraZeneca to run the study, which includes the AstraZeneca group of companies members, contractors, sub-contractors and any company that AstraZeneca goes into business with, or sells all or part of its business to, will be permitted to look at your personal information but they will not know who you are unless they are study inspectors.

All personal information obtained from this study are obliged to be kept by the study site and the sponsor for 25 years after the end of the study, unless there is a legal requirement for keeping them longer. Your coded data will be removed or anonymised at the end of this retention period.

You may get more information about how personal information is kept by AstraZeneca group of companies at www.astrazenecapersonaldataretention.com. Results will be used to know about rilvegostomig and for application for rilvegostomig to be approved for prescription to patients. It can also be used to respond to other queries which include safety of rilvegostomig.

Results obtained from this study will be published for example in medical journals or online, but you will not be stated in a way that would let people find out who you are. Researchers from for example AstraZeneca, other health-related companies, and universities may ask to use information obtained from this study, which include your information for other medical and healthcare-related research. The results from this study may be combined by the researchers with results from other studies.

AstraZeneca will find out what they wish to do before they share it. If your information is shared by the sponsor AstraZeneca will ensure that they cannot find out who you are.

Your personal information will be sent to another country(countries), to combine it with the information taken in the study, or for other reasons like 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 that have been approved by privacy authorities (called Binding Corporate Rules). Your personal information will still be stored completely private, irrespective of which country it goes to, even if that country does not have such strict data protection laws as India.

You may ask your study doctor to look at the information that has been taken about you. If you consider any of it is incorrect, you may ask the study doctor in writing if it may be changed or deleted. You may also ask that we restrict the use of your personal information. If you change your mind about giving information about yourself and your pregnancy, we will not be able to delete the personal information that was taken for this research study before you stopped the participation.

If you have any queries about how we use your personal information or would like a copy of the Binding Corporate Rules, kindly ask the study doctor first. You can 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 receive, you may complain to the Drugs Controller General (India).

WHOM MUST I GET IN TOUCH WITH IF I NEED ADDITIONAL INFORMATION OR HELP?

The plans for the study including this form have been reviewed by Institutional Ethics Committee.

If you have any queries about the research study, you may get in touch with the following:

Principal Investigator:	Dr. Prashant Pandey
Phone Number:	+91-9804290687
Email:	prashantpandeydr@gmail.com
Sub-Investigator/Study Coordinator:	
Phone Number:	
Hospital name and Address:	Tata Medical Center 14 MAR(E-W), Newtown, Rajarhat, Kolkata-700160

If you have any queries about your rights or research study, you can get in touch with the following:

Name of Ethics Committee	Institutional Review Board
Name of Ethics Committee's Member Secretary/Chairperson <i>(Member Secretary or Chairperson as applicable according to EC SOP)</i>	Dr. Indranil Mallick (Member Secretary)
Phone Number:	+91-9831171235

Trial Result Summaries are a short and easy way to understand summary of the results of this study. Within 1 year of the last study participants last site visit, these will be added to www.trialssummaries.com. You may visit www.trialssummaries.com website anytime to sign-up to be informed through email when the trial results summary of this study are available.

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

An explanation of this clinical trial will also be available on <http://www.clinicaltrials.gov>, as needed by U.S. Law. Information that may identify you will not be included in this website. Mostly, a summary of the results will be included in the website. At any time, you may search this website.

Information in the technical language associated with study protocol and the results will be posted on <http://astrazenecaclinicaltrials.com> and <https://www.clinicaltrialsregister.eu/> and/ euclinicaltrials.eu. An explanation of this study is also available on <http://ctri.nic.in>. Any information about you are not contained in these websites.

INFORMED CONSENT FORM

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By putting a signature on this form, you confirm the following:

- I have had time to read and think about this information and my queries have been answered appropriately.
- I agree to provide personal information about myself, my pregnancy, and my baby.
- I have been notified on the way my coded personal information might be taken, used and shared as explained in this document.
- I consent that my coded personal data may 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 cannot give informed consent (for example, an unconscious person or those with severe mental disease or disability), the same may be received from a legally acceptable representative (a legally acceptable representative is a person who can 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

The Patient Information Sheet (Pregnant Partners of Study Participants Information) and properly completed Informed Consent Form copy shall be given to the pregnant partner of study subject or her legally acceptable representative.