

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 regarding yourself and your pregnancy since you have become pregnant while your partner was participating in the research study D702NC00001 ARTEMIDE-Biliary02. Whether or not this information is shared by you is entirely up to you. Take the time you require for reading this form and ask any queries to the study doctor. You can speak to your family, friends or family doctor prior to you make a decision. In case you make a decision to let us have your information, you should put a signature on this form, to show that you consent to permit us to use your personal information.

WHY THE RESEARCH STUDY IS BEING PERFORMED BY US IN WHICH YOUR PARTNER IS PARTICIPATING IN?

Your partner consented to participate 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.

This research is being performed by AstraZeneca to find out whether the experimental medication known as rilvegostomig together with the use of chemotherapy (cisplatin and gemcitabine) will work and be safe for the biliary tract cancer treatment. Any health authority has not permitted Rilvegostomig, except for use in research studies such as this. AstraZeneca is paying the hospital / clinic /

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

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

All risks and side effects are not known for rilvegostomig. We do are not aware whether rilvegostomig can pass from the bloodstream into semen or whether it has any effects on sperm, pregnancy, or a baby prior to or post birth. We would like to gather information regarding you and your pregnancy, to see whether anything occurs that might be associated with rilvegostomig.

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

It is completely up to you whether or not you provide us information regarding your pregnancy.

At any time, you can make a decision to stop providing us information regarding your pregnancy, however you have to inform the study doctor. You do not have to explain your reasons for discontinuing, however it would be useful for us to know. In case you stop, you might still get in touch with the study doctor in case you want to get information regarding rilvegostomig.

WHAT DO I HAVE TO DO?

In case you consent, we will get in touch with you post you have given birth to your baby. We will ask you regarding your pregnancy and delivery and your baby's health. Also, in case you have a miscarriage or whether you make a decision to have an abortion, kindly get in touch with the study doctor.

The given below information will be gathered by us from you:

- Related medical history
- Any earlier pregnancies details, which includes outcome and any complications
- This pregnancy's Details
- At the time of this pregnancy, any drugs that you are taking
- This pregnancy's outcome
- Details regarding the birth of your baby and your baby

You will not be examined or any tests will not be performed by the study doctor. You will only be asked to answer queries and give information.

No payment will be given to you for providing us this information. Any costs associated with your pregnancy, delivery or your baby's care or any miscarriages or abortions will not be covered by us. The information regarding your pregnancy might assist us in understanding how the pregnancies are impacted by rilvegostomig.

WHAT IN CASE NEW INFORMATION BECOMES AVAILABLE?

You will be informed by us in case we get any new information on the rilvegostomig's effects on pregnancy.

HOW WILL MY PERSONAL INFORMATION BE HANDLED AND UTILIZED?

To get the answers we require, we have to collect personal information regarding you and your pregnancy. This consist of the answers to our queries regarding your pregnancy and earlier pregnancies. We will do everything we can to ensure that no one, except the study doctor/hospital/clinic and study inspectors, are aware about who you are. This is performed by us by using a code instead of your name and only these individuals will have the key to the code. Both the study doctor/hospital/clinic and AstraZeneca will ensure your personal information is secured. Health authorities and individuals helping AstraZeneca to run the study, which includes 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 permitted to see your personal information however they will not be aware 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 post the end of the study, unless there is a legal need for keeping them longer. Your coded data will be deleted or anonymised, at the end of this retention period.

You can find out additionally regarding how AstraZeneca group of companies keeps personal information at www.astrazenecapersonaldataretention.com. Results will be used for learning regarding rilvegostomig and for application for rilvegostomig to be permitted for prescription to patients. It might also be used to answer other queries which includes rilvegostomig safety.

Results from this study will be published e.g., in medical journals or online, however you will not be mentioned in a manner that would let individuals find out who you are. Researchers from e.g., AstraZeneca, other health associated companies, and universities might ask to use information from this study, which includes your information for other medical and healthcare related research. The results from this study might be combined with results from other studies by the researchers.

AstraZeneca will look at what they want to do prior to it is shared by them. In case your information is shared by the sponsor AstraZeneca will ensure that they cannot find out who you are.

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

You can ask your study doctor to see the information that has been gathered regarding you. You can ask the study doctor in writing if it can be changed or removed, in case you consider any of it is wrong. You can also ask that the use of your personal information is restricted by us. In case you change your mind regarding giving information about yourself and your pregnancy, the personal information that was collected for this research study before you stopped cannot be removed by us.

In case you have queries regarding how your personal information is used by us or want a copy of the Binding Corporate Rules, kindly ask the study doctor first. You might 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. You can complain to Drugs Controller General (India), in case you are unhappy with the answers you get.

WHOM MUST I GET IN TOUCH WITH IN CASE I REQUIRE ADDITIONAL INFORMATION OR HELP?

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

In case you have any queries regarding the research study, you can get in touch with:

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

In case you have queries regarding your rights or research study, you might get in touch with:

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 website within 1 year of the last study participants last site visit. At any time you can visit www.trialssummaries.com website to sign up to be notified through email when the trial results summary of this study is available.

Also, Trial Result Summaries will be posted on <http://euclinicaltrials.eu> website.

As needed by U.S. Law, a description of this clinical trial will also be available on <http://www.clinicaltrials.gov> website. Information that can recognize you will not be included on this website. Mostly, a summary of the results will be included on the website. At any time, you can search this website.

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

INFORMED CONSENT FORM

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By putting a signature on this form, you affirm the given below:

- I have had time to read and consider this information and my questions have been answered appropriately.
- I consent to provide personal information regarding myself, my pregnancy, and my baby.
- I have been informed on the way my coded personal information might be gathered, utilized and shared as explained in this document.
- I consent that my coded personal data can be used for other medical, healthcare or scientific related research objectives 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 unable to provide informed consent (for example, an unconscious individual or those suffering from severe mental illness or disability), the similar might be acquired from a legally acceptable representative (a legally acceptable representative is an individual who is able to provide consent for the pregnant partner of study subject as given 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

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