Recruitment & Informed Consent Procedure

EU trial number: 2024-518998-33-00

Study title: A Phase 3b, Multicenter, Randomized, Open-Label Study of Risankizumab Compared to Vedolizumab for the Treatment of Adult Subjects With Moderate to Severe Ulcerative Colitis Who are Naïve to Targeted Therapies

1. All clinical trials

This section should be completed for all trials

1.1. How will potential participants be identified *(e.g. publicising the trial or via existing patient lists)*

Subjects with moderate to severe ulcerative colitis (UC) will be enrolled by clinicians who are Principle Investigators (PIs) or Sub-Investigators (Sub-Is) for the study. Subjects may be identified through site local practice/patient database, or may be referred to the site by other local clinicians.

Eligible subjects include adults aged 18-80 with a diagnosis of UC for at least 90 days prior to the Baseline visit. Additionally, subjects must have moderate to severe disease activity at Baseline with a modified Mayo Score (mMS) of 5 to 9 points and Mayo Endoscopic Subscore (ESS) of 2 to 3 points (confirmed by central review). Subjects must also have demonstrated an intolerance or inadequate response to one or more of the following categories of drugs: aminosalicylates, oral locally acting steroids, systemic steroids (prednisone or equivalent), immunomodulators. Subjects must be naïve to Targeted Therapies. Subjects will also need to meet the other pre-determined eligibility criteria as outlined in the protocol.

1.2. What resources will be used for recruitment *(Describe the format of the resources, e.g. paper or electronic and how these will be presented to potential participants e.g. via the post, in the clinic, through social media or on the radio)*

Site staff will review their database for suitable patients and contact them to inform about the study.

1.3. Will identification of potential participants involve access to identifiable information? If yes, describe what measures will be in place to confirm that access to this information will be lawful *(in accordance with Member State requirements)*

Contact information for potential participants will be collected in the pre-screening process. This includes name, address, telephone number, and email address. Personal identifiable information will be available for the clinical site. Abbvie will not have access to any identifiable information.

1.4. Who will be approaching potential participants and who will be obtaining informed consent? *(Describe the professional role and whether there is a prior clinical relationship with potential participants)*

Appropriately trained site staff (i.e., Investigator, Study Nurse, Study Coordinator) will be responsible for identifying potential participants and will contact by phone, written communication (letter or email), or during a routine clinic visit. In all scenarios, site staff will be responsible for discussing details of the study with potential participants. The PI will ultimately

be responsible for answering all questions the study participant may have and obtaining informed consent.

1.5. When will free and informed consent be obtained? *(Describe when and where informed consent will be obtained and how privacy will be ensured)*

Potential participants will be provided a copy of the informed consent form to read and review. They will be given ample time to review the informed consent and all questions will be answered by the investigator to the participants' satisfaction prior to any study procedures being performed. The site is responsible to ensure participant confidentiality is upheld. If the potential participant decides that they would like to participate in the study, the informed consent will be signed by the participant and the investigator. Optional samples will be collected only if the potential participant gives consent for collection. As the informed consent contains patient identifying information, it will not be collected by the sponsor or removed from the investigator's office.

1.6. How long will potential participants (or their legal representative) be given to decide whether to participate?

Potential participants will be given as much time as needed to review the informed consent, discuss and or ask any questions from the investigator or a member of the research team. By choice, potential participants can discuss the informed consent with friends, family, and general practitioner before deciding to participate. Please note, as the recruitment for this study is competitive, there is no guarantee that enrollment will be open when/if the patient decides to participate. Legally Authorized Representatives (LARS) are not required for this study.

1.7. How will it be assured that potential participants (or their legal representative) have understood the information and that consent is informed? *(Include how the informational needs of individuals will be identified and addressed)*

The investigator will explain the nature of the study and risks anticipated from participation in the study to the potential participant, and answer all questions regarding this study. Prior to any study- related screening procedures being performed, the informed consent form will be reviewed, signed, and dated by the potential participant, the person who administered the informed consent, and any other signatories according to local requirements. A copy of the signed informed consent will be given to the participant. The ICFs will be provided in the local language written to an appropriate reading level for the potential study participant. The site's ability to ensure the participant's understanding of the informed consent will be evaluated as part of the site evaluation process. Legally Authorized Representatives (LARS) are not required for this study.

1.8. What arrangements are in place to obtain informed consent from potential participants (or their legal representative) who do not speak the national language?

Informed consent forms will be approved by ethics committees in the local language. Potential participants must be able to understand the informed consent form and to ask questions in discussion with the investigator in local language. Legally Authorized Representatives (LARS) are not required for this study.

1.9. How will it be ensured that participants can withdraw their consent at any point? *(Include how any potential consequences of consent withdrawal will be dealt with)*

The study participant will receive a copy of their signed informed consent. The informed consent will include language confirming that study participation is voluntary, and the participant has the right to withdraw consent at any point without having to provide a justification, with no penalty or loss of benefits to which the subject is otherwise entitled, and the decision will not affect the participant's regular medical care.

1.10. Provide any further information, in relation to the procedure for recruitment and informed consent for the clinical trial, which has not been provided elsewhere in this document. *(Refer to national guidance to ensure that all required information has been provided)*

N/A

1.11. In case this form is used also to describe recruitment arrangements (Annex I K59), please provide a clear indication of what the first act of recruitment is.

First act for recruitment on the study will be for sites to review their database/own practice and the sites will have the option to choose if they wish to use any recruitment resources offered by the Sponsor. Obtaining informed consent would be the first procedure the patient undergoes related to the study.

The EUCTR notification for Start of Recruitment will be submitted when the first subject signs the informed consent.

2. Clinical trials which will recruit incapacitated adults

Incapacitated adults may be recruited into clinical trials only where consent has been obtained from a legally designated representative and data of a comparable validity cannot be obtained in clinical trials involving participants who are competent to give informed consent. Where potential participants do lack capacity to consent, arrangements should be in place to involve them as much as possible in the decision to participate in the clinical trial

☒ **This section is not applicable**

2.1. Provide justification for recruiting incapacitated adults *(Include details of the nature of the condition which has caused the person to be incapacitated and the relevance of this condition to the clinical trial)*

2.2. Who will assess and confirm whether a potential participant has the capacity to consent?

2.3. Where capacity to consent will fluctuate or will be borderline, how will potential participants be involved in the decision to participate in the trial? *(Include how information will be tailored to ensure participants (potential and existing) are able to understand the information and how participants who regain capacity will be consented to continue in the trial)*

2.4. How will a legal representative be identified? *(Include which roles could act as legal representative for this trial)*

3. For clinical trials which will involve minors

Minors may be recruited into clinical trials only where consent has been obtained from a legally designated representative and where the clinical trial is such that it can only be carried out on minors. The minor should take part in the informed consent procedure as much as would be appropriate based on age and mental maturity. Where it would be appropriate, specify any different arrangements for different age ranges.

☒ **This section is not applicable**

3.1. Provide justification for recruiting minors

3.2. How will potential participants be involved in the decision to participate in the trial? *(Describe arrangements for obtaining and recording assent, including who will be obtaining consent and details of their training and experience with children)*

3.3. How will a legal representative be identified? *(Include which roles could act as legal representative for this trial)*

3.4. How will participants be consented to continue in the trial when they reach the age of legal competence?

4. Clinical trials where consent witnessed by an impartial witness will likely be used

Where a participant is unable to write, consent may be given and recorded through appropriate alternative means in the presence of at least one impartial witness. The witness is required to sign and date the informed consent document.

☒ **This section is not applicable**

4.1. Why is it expected that an impartial witness might be required?

4.2. How will an impartial witness be identified?

4.3. How will it be known that the potential participant gives their informed consent?

5. Clinical trials in an emergency situation

Information on the clinical trial may be given and informed consent may be obtained after the decision to include the participant in the clinical trial. This is where the decision is taken at the time of the first intervention in accordance with the protocol and, due to the urgency of the situation, the person is unable to give consent, nor can a legal representative be identified.

☒ **This section is not applicable**

5.1. Describe why it would not be possible to obtain consent from potential participants or a legal representative prior to recruiting into the clinical trial.

5.2. What arrangements will be in place to obtain informed consent from the participant or from a legal representative, whichever can be obtained soonest? *(Where a legal representative is expected to be required due to the participant not having capacity to consent, also complete section 2 of this document)*

5.3. How will it be ensured that a potential participant has not expressed any previous objection to participate in the clinical trial?

6. For 'cluster' clinical trials

Informed consent may be obtained by simplified means where this does not contradict national law, the methodology of the trial requires the randomisation of groups rather than individuals, the investigative medicinal product is being used in accordance with the terms of the marketing authorisation and there are no interventions other than standard treatment. Clear justification for simplified consent should also be included in the protocol.

☒ **This section is not applicable**

6.1. Describe how simplified informed consent will be obtained?