Contact Details

Study Doctor Name: _____

Study Site Number: _____

Study Site Location: _____

_____

Emergency Number: _____

UNLIMMITED

Your Guide to Clinic Visits

UnlIMMited Study

A clinical research study for adults seeking treatment for psoriasis affecting the genitals or scalp.

Welcome to the UnlIMMited Clinical Study

Thank you for choosing to sign up for the UnlIMMited study. The purpose of this study is to see if the study drug (risankizumab) is safe and effective in treating signs and symptoms of psoriasis affecting the genitals (Study-G) or scalp (Study-S). During your participation in the UnlIMMited study, all study-related care will be provided at no cost.

Your participation in this study is completely voluntary. You may choose to stop at any time without further explanation. You will not be punished or lose any benefits to which you are otherwise entitled. Thanks to you, and your commitment to complete the necessary activities in this study, we can better understand how risankizumab affects those with moderate to severe genital and scalp psoriasis.

Use this guide throughout your time in the study to understand what to expect at each clinic visit. If you have any questions, please do not hesitate to ask your study doctor or nurse.

Overview of the UnlIMMited Study

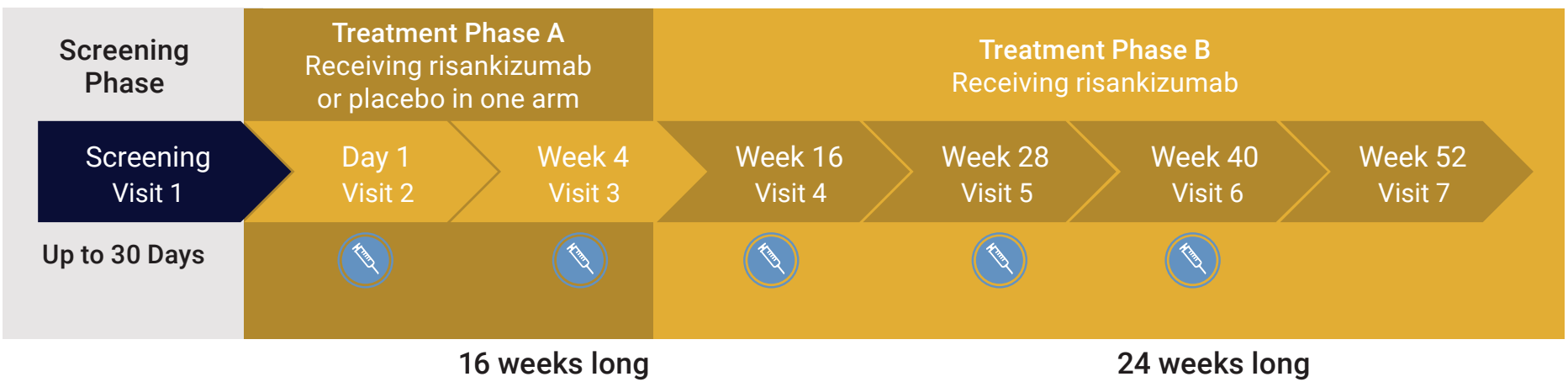
Approximately 200 adult participants (100 in Study-S and 100 in Study-G) with a clinical diagnosis of chronic plaque psoriasis which is currently affecting the genitals and/or scalp and meeting specific severity criteria will be enrolled.

At the Baseline/Day 1 visit and Week 4 visit, half of all participants will be administered a single, subcutaneous injection (injection under the skin) of risankizumab while the other half will receive a matching injection of placebo (a substance with no anticipated effect on the body). All subjects will receive one subcutaneous injection of risankizumab during the visits at Weeks 16, 28, and 40.

The study doctor, or qualified site staff, will assess your psoriasis throughout the study. Questionnaires will ask about any psoriasis symptoms you experience and the impact of psoriasis on your daily life.

Overview of the 64-week study timeline:

Study participation will be approximately 64 weeks, including a screening period (1-30 days) in which your eligibility for the study will be determined, a 16-week placebo-controlled treatment period in which you will not know if you receive study drug or a matching placebo (Period A), a 36-week open-label treatment period in which all subjects will receive study drug (Period B), and an 8-week follow-up period.



Screening Phase

If you decide to take part in the study, you will start with a Screening visit at the research center. There is a Screening period up to 30-days during which your study doctor will determine if you meet the study requirements and if you are eligible to participate in the study.

Treatment Phase A

During this period, you will need to go to the study site for the Baseline (Day 1) visit and the Week 4 visit. You will be given an injection of risankizumab or placebo at both visits. There is a 50/50 chance (like flipping a coin) that you will be assigned to the placebo or risankizumab group.

Treatment Phase B (Open-Label Treatment Period)

During Period B, which starts at Week 16, you will be given a subcutaneous injection of risankizumab, no matter which treatment you were receiving during Period A. Period B includes visits at Weeks 16, 28, and 40. The last study visit to the research center will be at Week 52, to perform another assessment of your health, skin, and psoriasis.

Study Activities

Subject Information and Informed Consent
This was the first step you took to participate in this study. You received, reviewed and signed the informed consent form, which describes what will happen during the study, including known risks and benefits.

Assess Eligibility Criteria
Before you are enrolled in the UnIIMMited study, the study site staff will make sure you meet the criteria that qualifies you for this study.

Demographics
Personal information such as your date of birth, gender and race will be collected.

Electronic Questionnaires
You will be asked to answer some questions on an electronic device to understand your psoriasis and your response to the study drug. Questions will relate to pain or itch you may have, the impact on your quality of life, emotions, work life, and will document your feelings of the disease severity.

You will be given a handheld device at the beginning of the study to take home until Week 16, since some questions will need to be answered at home every day, or every week. Other questions will only need to be answered during the study visits in the clinic on a site device. If you do not qualify to participate in the study, you will need to return the device right away. If you do qualify, you will return it at the Week 16 visit.

The device meets all regulations for use in clinical studies, including those related to your privacy. Your answers to the questions will be transferred to a storage facility via a secure internet connection and will be viewed by site and AbbVie.

Instructions will be provided with the instrument. You are to provide the most accurate response to each item. Site personnel shall not provide interpretation or assistance to you other than encouragement to complete the tasks.

Psoriasis Assessments
The study doctor will assess your skin and psoriasis.

Physical Examination
The study site staff will perform a general check of your health, similar to physical exams performed by your family doctor.

Vital Signs
Includes blood pressure, heart rate, respiratory rate, and temperature.

Electrocardiogram (ECG)
A machine will record the electrical activity of your heart.

Height and Weight
Your height and weight will be measured.

Medical and Surgical History
The study site staff will ask about your medical history including cosmetic, dental, and surgical procedures. You will also be asked about your nicotine, alcohol and drug use.

Adverse Event Assessment
We will ask you how you are feeling and if you have experienced any health problems, which may or may not be related to the study drug.

Review Current Medications
We will ask you about the medications that you are currently taking and if there have been any changes in these medications since your last visit.

Assessment of Latent Tuberculosis (TB)
Questionnaire to assess risk factors for tuberculosis.

Tuberculosis (TB) Test
A blood test or injection under the skin will be done to see if you have been exposed to tuberculosis.

Pregnancy Test
A sample of urine will be collected to test if you are pregnant. You will only have pregnancy testing if you are a woman and can have children. The study doctor or study staff will tell you if the pregnancy test results are positive. The results of the pregnancy testing must be negative in order for you to continue in the study.

Blood Sample Collection
We will draw a sample of your blood for lab tests to monitor your health. If you are a woman able to have children, your blood will also be tested for a potential pregnancy at the screening visit.

Urine Sample
A urine sample will be collected to perform laboratory tests.

Photography
You may choose to have photographs taken to document the response of your psoriasis to the study drug treatment. This will only be done at a selection of sites in the United States.

Study Drug Injections
You will receive a dose of study drug (or placebo) at the study center. All doses are subcutaneous injections (injection under the skin) that will be administered by designated and qualified study site personnel under the direction of the study doctor during your scheduled visits.

Hypersensitivity Monitoring
You will be monitored for any reaction to the study drug for about 1 hour after receiving a dose of the study drug.

Notes

Study Procedures

Screening (Visit 1)

- Subject Information and Informed Consent
- Demographics
- Eligibility criteria
- Current and prior medications
- Physical examination and vital signs
- Blood draw
- Medical and surgical history
- ECG
- Medication history
- Psoriasis assessments
- Electronic questionnaires
- Urine sample
- Assessment of latent TB
- TB test

Study Procedures

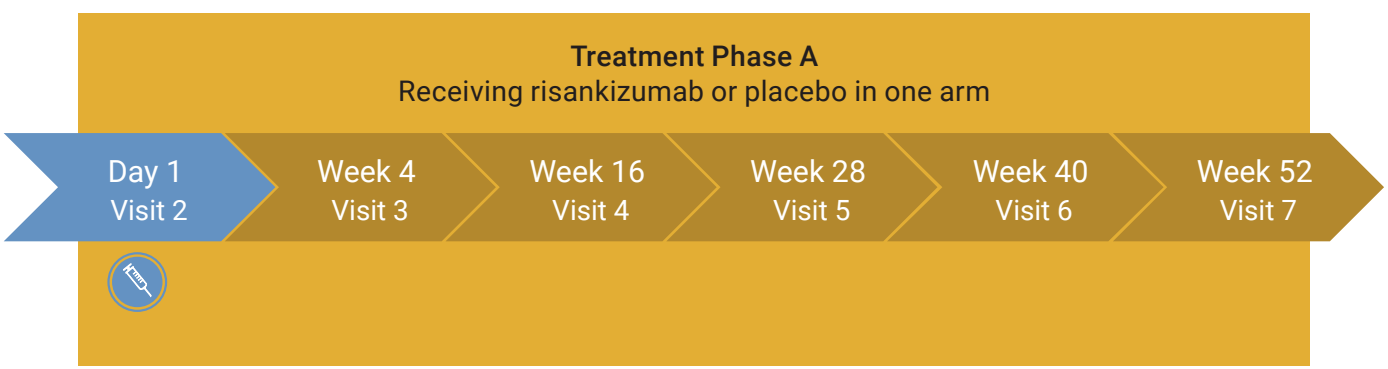
Period A Baseline Day 1 (Visit 2)

- Eligibility criteria
- Psoraisis assessments
- Administration of study drug or placebo
- Review current medications
- Photography (optional)
- Hypersensitivity monitoring
- Physical examination and vital signs
- Urine pregnancy test (for all female subjects of childbearing potential)
- Electronic questionnaires
- Medical and surgical history
- Blood draw

Date:

Time:

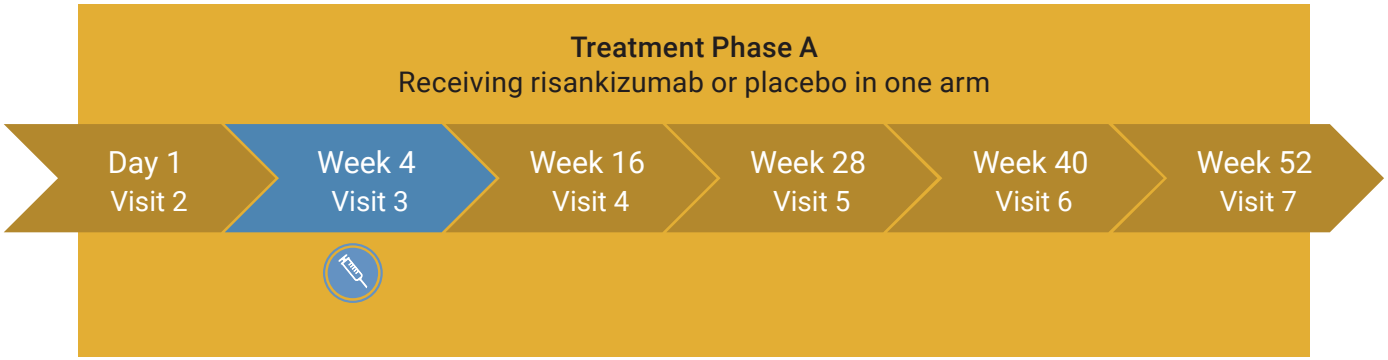
Notes:



Study Procedures

Period A Week 4 (Visit 3)

- Adverse event assessment
- Photography (optional)
- Electronic questionnaires
- Review current medications
- Urine pregnancy test (for all female subjects of childbearing potential)
- Psoriasis assessments
- Administration of study drug or placebo
- Vital signs
- Hypersensitivity monitoring



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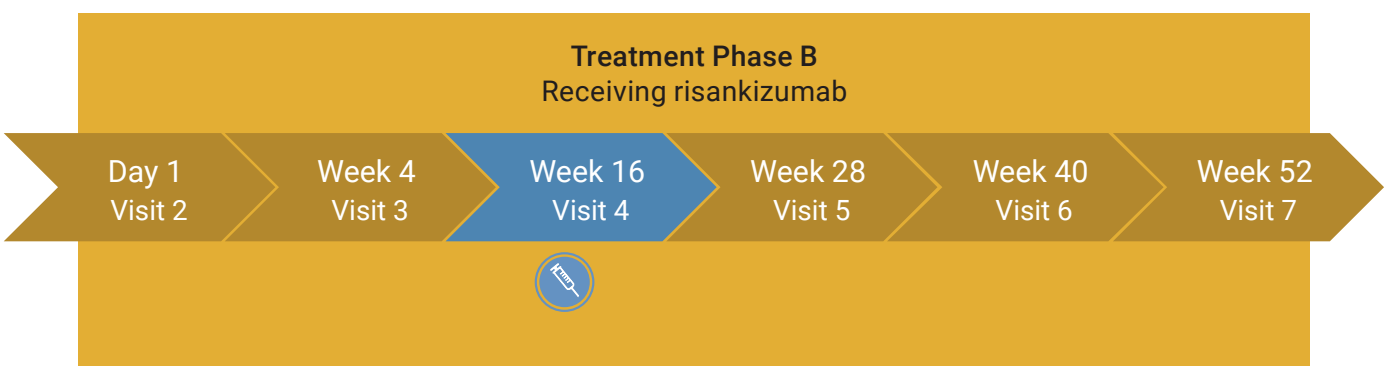
Study Procedures

Period B Week 16 (Visit 4)

- Adverse event assessment
- Photography (optional)
- Electronic questionnaires
- Review current medications
- Urine pregnancy test (for all female subjects of childbearing potential)
- Psoriasis assessments
- Administration of study drug
- Vital signs
- Hypersensitivity monitoring



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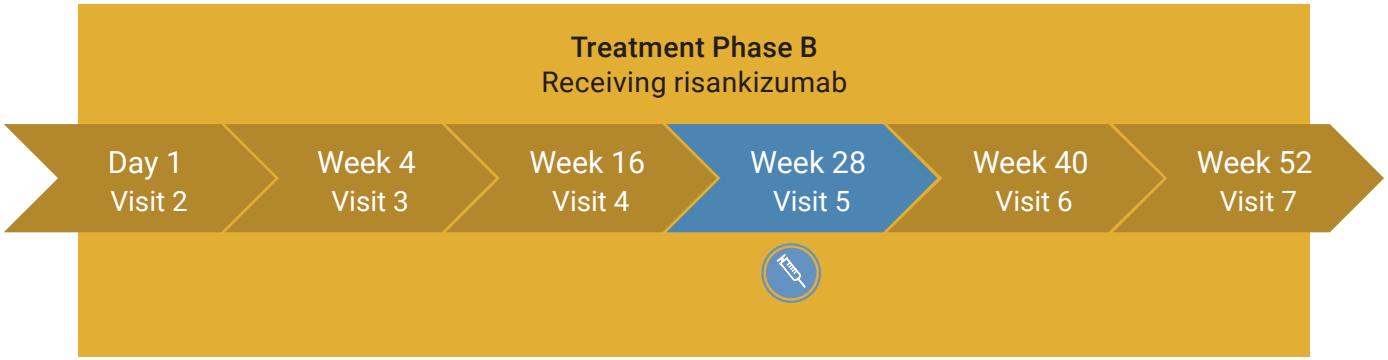
Study Procedures

Period B Week 28 (Visit 5)

- Adverse event assessment
- Photography (optional)
- Hypersensitivity monitoring
- Review current medications
- Urine pregnancy test (for all female subjects of childbearing potential)
- Electronic questionnaires
- Psoriasis assessments
- Blood Draw
- Vital signs
- Administration of study drug



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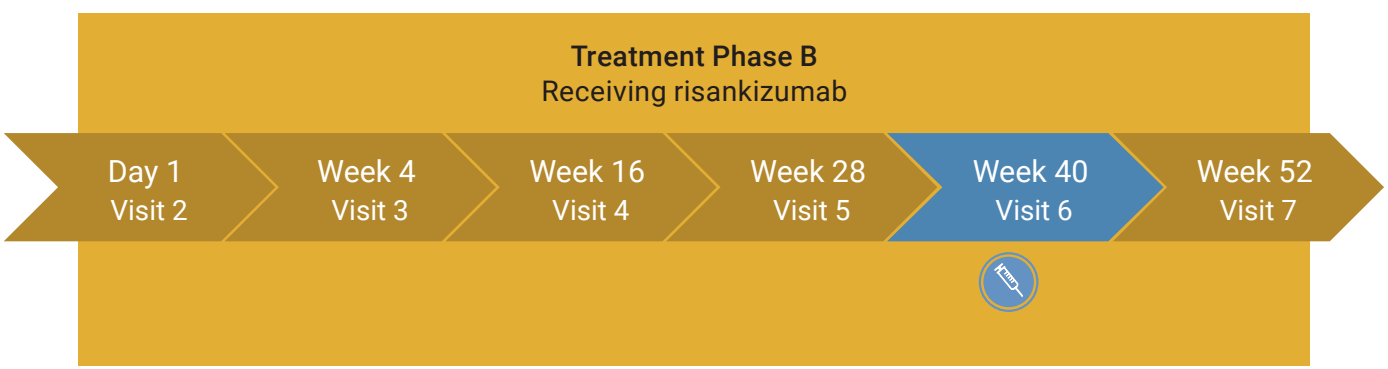
Study Procedures

Period B Week 40 (Visit 6)

- Adverse event assessment
- Photography (optional)
- Electronic questionnaires
- Review current medications
- Urine pregnancy test (for all female subjects of childbearing potential)
- Psoriasis assessments
- Administration of study drug
- Vital signs
- Hypersensitivity monitoring



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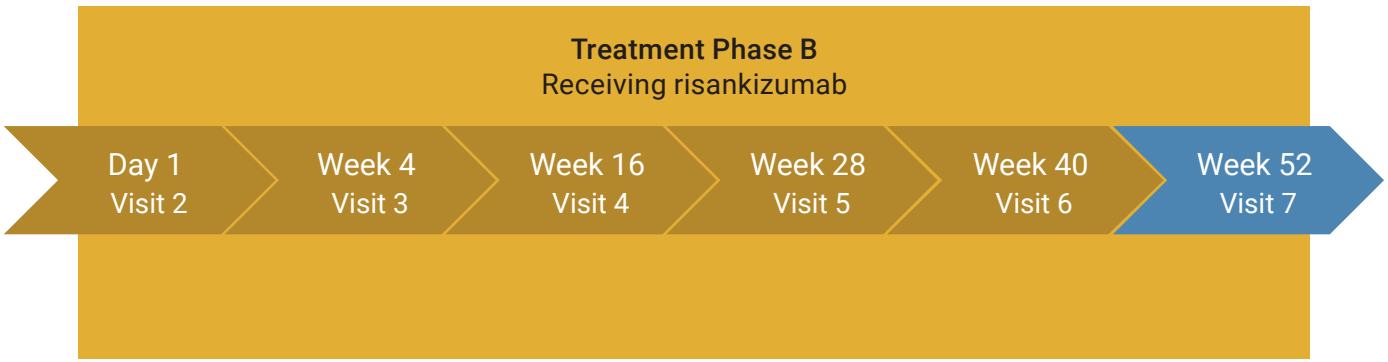
Study Procedures

Period B Week 52 (Visit 7)

- Adverse event assessment
- Weight
- Electronic questionnaires
- Review current medications
- Physical exam
- TB Test
- Psoriasis assessments
- Photography (optional)
- Vital signs
- Blood draw



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Study Procedures

Follow-Up Phone Call / 20 Weeks After Last Study Drug Dose (approximately 8 weeks after the Week 52 visit)

Adverse event assessment

Review current medications

Note: Does not apply to subjects who initiate commercial risankizumab or continue in the optional Continuous Treatment Extension.

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