

We're in your
corner in the fight
against pouchitis

LET'S
HOP
TO IT!



Visit Guide



Study contact information

Study doctor:

Study coordinator:

Study staff contact:

Key phone numbers:

Key email addresses:

Please note that in this visit guide, “you” refers to the person taking part in the study.



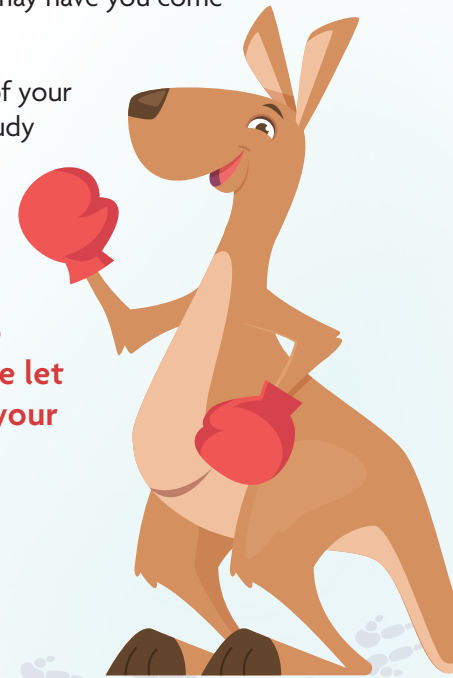
Welcome to the Kangaroo study!

This clinical study is testing an investigational medication called vedolizumab in children and teens with active chronic pouchitis. Vedolizumab is not approved for use in treating pouchitis in this age group. It is available to people under the age of 18 only in this study.

You will have scheduled study visits for study treatment and tests and procedures to assess your pouchitis and your overall health. Study treatment with vedolizumab will be given by intravenous infusion. This means the infusions will be given through a small tube that is inserted into a vein in your arm. Your study doctor may have you come to more visits depending on your health.

You can use this Visit Guide to keep track of your visits and what will happen at them. The study team will explain the tests and procedures and answer any questions you may have. You will have their full support at all times in this study.

We appreciate all you are doing to support the Kangaroo study. Please let us know what we can do to make your study experience better.



Rescheduling a visit

It is very important to come to all your visits. If you will not be able to make it to a visit, please let your study team know. They will work to reschedule the visit at a time that works.

Your responsibilities

Clinical studies rely on the cooperation of the volunteer participants. While you are in this study, you will need to:

- Follow instructions from your study team
- Come to your study visits and have tests and procedures done
- Take an antibiotic medication for part of the study (unless you are allergic or cannot for some other reason)
- Have infusions of the study medication (vedolizumab)
- Tell your study team if you are feeling sick
- Tell a parent or someone else who takes care of you if you feel sick between visits
- Use the study diary to record symptoms you have before some visits
- Talk with your study team before you start taking any new medicines, vaccines, vitamins, or supplements
- Tell your study team if you want to stop being in the study

Extension study

You may be able to continue receiving vedolizumab after this study if:

- You complete this study.
- Tests show that your health is improving.
- You want to continue.

Study tests and procedures

The study team will explain each of these to you and answer any questions you may have. Visits may also include tests and procedures not listed here.

Informed consent and paediatric assent	Review of the study, including potential risks and benefits and what you will need to do if you participate
Review of medical and surgical history	Review of current and prior health conditions, treatments, and surgeries
Review of pouchitis disease history	Review of your current and prior pouchitis symptoms
Review of other medications and procedures	Discussion about medications you can take and procedures that are not part of the study
Physical exam	Assessment that may include eyes, ears, nose, throat, heart, lungs, stomach, skin, arms, legs, muscles, bones, nervous system, lymph nodes, and tanner staging (tracking physical development during puberty)
Weight and height	Measurements taken at each visit
Vital signs	Measurement of body temperature, respiratory rate, blood pressure, and heart rate
Questionnaire	Questions about how your health affects your daily life
Study diary completion	Review of symptoms recorded in a study diary
Pouch endoscopy with biopsy	Procedure to look at your ileal pouch and collect a tissue sample from it
Blood sample collection	For routine laboratory tests
Urine sample collection	For routine laboratory tests
Stool sample collection	To check for intestinal inflammatory activity
Pregnancy test (if applicable)	If you are female and old enough to become pregnant
Vedolizumab infusion	Study treatment given through a small tube inserted into a vein in your arm
Review of adverse events and side effects	Discussion about how you are feeling and any side effects that you may have

Screening Visit

DATE _____

TIME _____

TESTS AND PROCEDURES

- Informed consent and paediatric assent
- Review of medical and surgical history
- Review of pouchitis disease history
- Review of other medications and procedures
- Physical exam
- Weight and height
- Vital signs
- Study diary completion
- Pouch endoscopy with biopsy
- Blood sample collection
- Urine sample collection
- Stool sample collection
- Pregnancy test (if applicable)

Notes

Day 1

DATE _____

TIME _____

TESTS AND PROCEDURES

- Review of other medications and procedures
- Physical exam
- Weight and height
- Vital signs
- Questionnaire
- Blood sample collection
- Urine sample collection
- Stool sample collection
- Pregnancy test (if applicable)
- Vedolizumab infusion
- Review of adverse events and side effects

Notes



Week 2

DATE

TIME

TESTS AND PROCEDURES

- Review of other medications and procedures
- Physical exam
- Weight and height
- Vital signs
- Pregnancy test (if applicable)
- Vedolizumab infusion
- Blood sample collection
- Review of adverse events and side effects

Notes

Week 6

DATE

TIME

TESTS AND PROCEDURES

- Review of other medications and procedures
- Physical exam
- Weight and height
- Vital signs
- Pregnancy test (if applicable)
- Vedolizumab infusion
- Blood sample collection
- Review of adverse events and side effects

Notes

Week 14

DATE _____

TIME _____

TESTS AND PROCEDURES

- Review of other medications and procedures
- Physical exam
- Weight and height
- Vital signs
- Questionnaire
- Study diary completion
- Pouch endoscopy with biopsy
- Blood sample collection
- Urine sample collection
- Stool sample collection
- Pregnancy test (if applicable)
- Vedolizumab infusion
- Review of adverse events and side effects

Notes

Week 22

DATE _____

TIME _____

TESTS AND PROCEDURES

- Review of other medications and procedures
- Physical exam
- Weight and height
- Vital signs
- Stool sample collection
- Pregnancy test (if applicable)
- Vedolizumab infusion
- Blood sample collection
- Review of adverse events and side effects

Notes

Week 30

DATE _____

TIME _____

TESTS AND PROCEDURES

- Review of other medications and procedures
- Physical exam
- Weight and height
- Vital signs
- Blood sample collection
- Urine sample collection
- Stool sample collection
- Pregnancy test (if applicable)
- Vedolizumab infusion
- Review of adverse events and side effects

Notes

Other Visits (if needed)

DATE _____

DATE _____

TIME _____

TIME _____

DATE _____

TIME _____

TESTS AND PROCEDURES

- Review of other medications and procedures
- Physical exam
- Weight and height
- Vital signs
- Study diary completion
- Blood sample collection
- Urine sample collection
- Stool sample collection
- Review of adverse events and side effects

Notes

Week 34

DATE _____

TIME _____

TESTS AND PROCEDURES

- Review of other medications and procedures
- Physical exam
- Weight and height
- Vital signs
- Study diary completion
- Questionnaire
- Pouch endoscopy with biopsy
- Blood sample collection
- Urine sample collection
- Stool sample collection
- Pregnancy test (if applicable)
- Review of adverse events and side effects

Notes

Week 48 (or 18 weeks after last infusion)

DATE _____

TIME _____

TESTS AND PROCEDURES

- Review of other medications and procedures
- Physical exam
- Weight and height
- Vital signs
- Pregnancy test (if applicable)
- Blood sample collection
- Review of adverse events and side effects

Notes

