

IVIG or Saline Placebo Participant Schedule

Keep this schedule in a safe place so you can refer to it throughout the study.

STUDY ACTIVITIES: About 12 months (1 year)

Pre-Study Period (3 weeks)

Baseline Visit
(about 5.5
hours)

Date:

Information

- Review current medicines
- Review study requirements
- After this visit, complete a survey about how you are feeling

Assessments

- Surveys
- Blood sample
- Nasal swab sample
- Skin samples
- Physical ability tests
- Safety check
- Pregnancy test, if needed
- Autonomic nervous system function tests (only at specific sites)

Receive

- Fitness tracker
- At-home stool (poop) sample kit
- Coordinated non-drug care group
 - Blood pressure and heart rate machine
 - Salt measurement spoons
 - Water bottle
 - Compression belt
 - Yoga mat
 - Latex stretch bands
 - Physical activity training guidelines
 - Weekly activity log
- Usual non-drug care group
 - Magnet with guidance on lifestyle and diet changes

Study Treatment Period (9 months)

Begin Weekly Infusions of the Study Drug

- Visit the infusion center about once a week for 9 months (about 36 visits). The study team may make changes to your infusion schedule depending on how you react to the infusion
- The study team will schedule you for all infusions
- You will receive either IVIG or saline placebo through an intravenous (IV) needle at each visit, plus fluids and medicines to help prevent or reduce side effects
- The study team will monitor your vital signs (such as blood pressure and heart rate) before and after the infusions

Begin Coordinated Non-Drug Care, If Assigned

- If you are in this group, you will be asked to complete a non-drug care log to record your activities at the end of each week.
- Activities include checking your blood pressure and heart rate, eating salt, drinking water, wearing a compression belt, and completing physical activities.
- A care coordinator will contact you once a week for 3 months to provide support on these activities

Study Treatment Period (9 Months), continued

3-month
Clinic Visit
(about 1.5 hours)

Date:

Information

- Review how consistently you have completed the study treatment
- After this visit, complete a survey about how you are feeling

Assessments

- Surveys
- Physical ability tests
- Safety check

6-month
Clinic Visit
(about 1.5 hours)

Date:

Information

- Review how consistently you have completed the study treatment
- After this visit, complete a survey about how you are feeling

Assessments

- Surveys
- Physical ability tests
- Safety check

9-month
End of Treatment
Visit
(about 5 hours)

Date:

Information

- Review medicines
- Review how consistently you have completed the study treatment
- After this visit, complete a survey about how you are feeling

Assessments

- Surveys
- Physical ability tests
- Blood sample
- At-home stool (poop) sample kit
- Safety check
- Autonomic nervous system function tests (only at specific sites)
- Skin samples, if needed

Follow-Up: End of Study (3 months later)

12-month End of Study Visit (about 2 hours)

Date:

Information

 After this visit, complete a survey about how you are feeling

Assessments

- Surveys
- Physical ability tests
- Blood sample
- Safety check