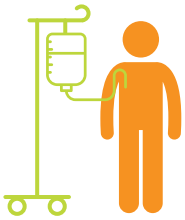
STARS - a Patient-Centered Study of Apraglutide in Short Bowel Syndrome with Intestinal Failure: Study Design

What is short bowel syndrome with intestinal failure?

Short bowel syndrome (SBS) is a rare condition in which large parts of the intestine have been removed by surgery and the remaining intestine does not work properly. In severe cases, people with SBS can't absorb enough nutrients and fluids from eating and drinking. This is called **SBS with intestinal failure (SBS-IF).**

SBS-IF affects about
18,000 adults
U.S., Europe, and Japan

What is the goal of treatment?



People with SBS-IF often need artificial nutrition and/or hydration, known as parenteral support (PS). This is also sometimes known as total parenteral nutrition (TPN). The SBS symptoms and the need for PS can restrict daily activities and quality of life. People with SBS-IF are also at risk of complications, such as infection.

The ultimate goal of treatment is to improve the gut's absorption of nutrients to maintain health and weight, so that the need for PS can be reduced or sometimes removed completely.

PS is a nutritional formulation in a bag that delivers nutrients and fluid directly into the blood via a tube into a vein.

What is apraglutide?

Apraglutide is an investigational drug, which means it has not been approved as a medicine. It is being studied in the STARS study.

GLP-2 is a hormone produced by the intestine to increase nutrient and fluid absorption. People with SBS-IF may have lost the cells that produce GLP-2 following surgery or damage to the bowel.

Apraglutide is designed to act like natural GLP-2:

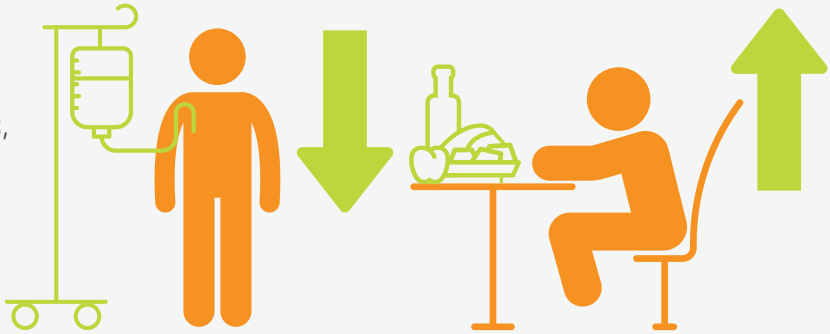
Given once weekly

As an injection under the skin

What is the STARS study looking at?

STARS is the largest global study of a GLP-2 therapy in people living with SBS-IF.
The study investigated the safety and effectiveness of apraglutide. It aims to find out if apraglutide is effective in reducing the need for PS, and if there is an improved absorption of nutrients and fluids from normal eating and drinking.

Researchers tested if apraglutide can reduce the volume and time needed on PS, allow more PS-free days, or even remove the need for PS in some patients.



How was the STARS study designed around patient needs?

A **patient-centered** approach was used to:

- Match patient priorities through patient-reported outcomes
- Optimize personalized care and outcomes specific to an individual's remaining intestine
- If eligible for the study, help patients take part through at-home nurse visits, travel support and digital technology

In addition to finding out if apraglutide is effective in decreasing the need for PS, STARS was designed to find out:

- How well apraglutide works depending on the parts of an individual's remaining intestine, such as in people with a stoma or no stoma (preserved colon)
- How apraglutide impacts quality of life, by measuring factors such as diarrhea or stoma output, sleep disturbances, and physical activities
- The safety and tolerability of apraglutide

Who took part in the STARS study and how was it organized?

Participants

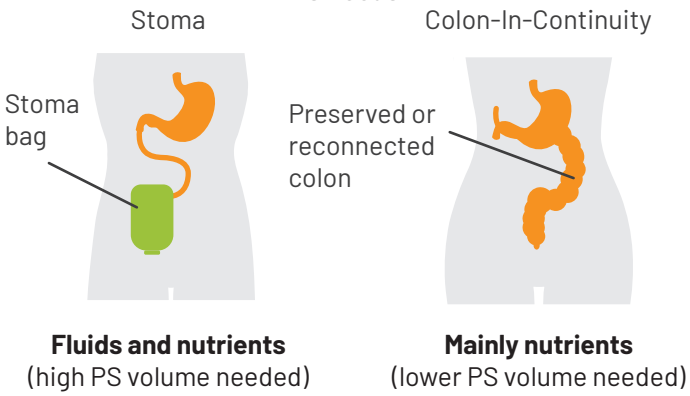
- People with SBS-IF
- At least 18 years old
- Needing PS at least 3 days per week
- People with a stoma or no stoma (preserved colon)

Treatment groups

Participants were grouped based on if they had

1) a stoma, or
2) a preserved colon (colon-in-continuity; CIC)

PS needs

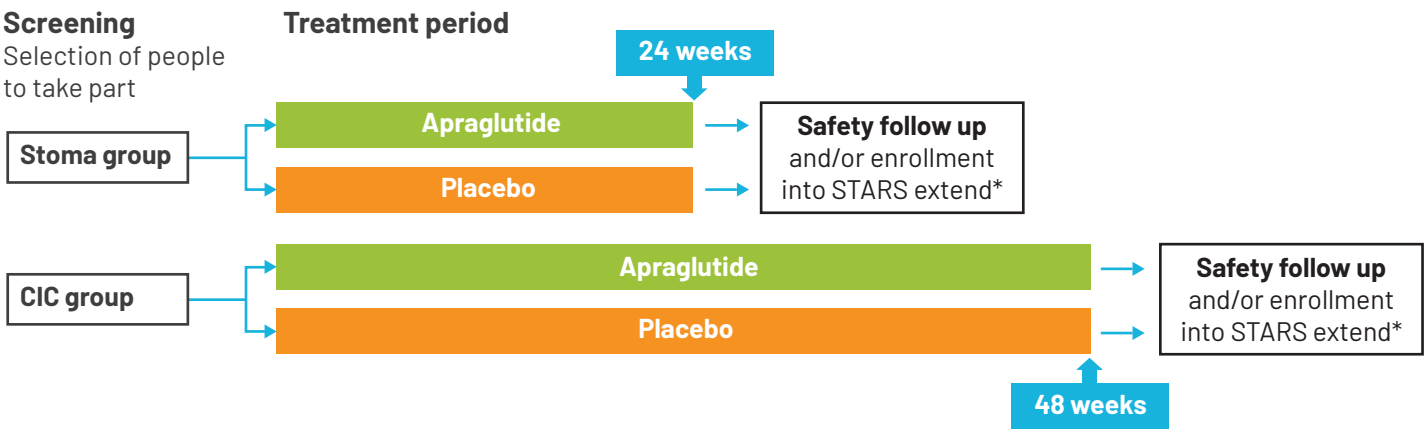


Fluids and nutrients (high PS volume needed)

Mainly nutrients (lower PS volume needed)

- 164 participants, from 18 countries, were randomly assigned (by chance) to receive apraglutide or placebo
- 163 participants received treatment (around 50:50 stoma and CIC participants)
- Participants administered trial treatment themselves once a week

Placebo looks like the study drug apraglutide but contains no active ingredient.
STARS was a **'double-blind'** study. This means that neither the participants nor the trial staff knew which treatment group participants were in.



*The long-term effectiveness and safety of apraglutide are continuing to be studied in the 2-year STARS extend study.

You can find out more about the STARS study at the following study registration website: https://clinicaltrials.gov/study/NCT04627025.
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The researchers would like to thank the participants for their contributions to the study.

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