

MS1819-SD phase IIa clinical trial for patients with exocrine pancreatic insufficiency (EPI) caused by chronic pancreatitis (CP) and/or distal pancreatectomy.

ACTRN12616000962437

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| Status | RECRUITING |
| Sponsor | INC Research Australia Pty Ltd |
| Enrollment | 13 participants |

Plain Language Summary

This study is for people with chronic pancreatitis (long-term inflammation of the pancreas) or who have had part of their pancreas removed, and as a result cannot properly digest fat. The pancreas normally makes enzymes to digest food, and when it cannot, people can develop greasy diarrhea, urgency, and weight loss. This trial tests a new enzyme replacement medicine called MS1819-SD at different doses to find out if it is safe and helps digestion.

You may be eligible if:

- You are 18 years of age or older
- You have chronic pancreatitis or have had a distal pancreatectomy (partial pancreas removal)
- Blood tests show your pancreas is not making enough enzymes
- You are within a certain weight range

You may NOT be eligible if:

- You have cystic fibrosis
- You have had your entire stomach or most of your duodenum removed
- You have celiac disease, small bowel disease, or significant small bowel removal
- You had an acute pancreatitis attack within the last 3 months
- You have active or recurrent pancreatic cancer
- You are pregnant or breastfeeding

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (9)

- Signed and dated informed consent form,
- Age 18 years and older,
- Male or female,
- Body weight within the range [50-100 Kg] for males or [40-90 Kg] for females,
- Distal pancreatectomy for any disorder (e.g. acute pancreatitis or its complications, CP or its complications, pancreatic endocrine or exocrine cancer, or others) and/or CP of any etiology (e.g. alcohol, genetics, hypercalcemia, or others) of grade 2 or higher (Cambridge classification),
- ... and 4 more (see full listing online)

Exclusion (10)

- Cystic fibrosis,
- Total or partial gastrectomy,
- Cephalic or total duodenopancreatectomy,

<https://documentcloud.clinicaltrialsfinder.org.au/TrialReview.aspx?ACTRN=ACTRN12616000962437>

- Any small bowel disease possibly responsible for malabsorption, including small intestinal bacterial overgrowth, celiac disease, small bowel resection greater than or equal to 1 meter length, etc.,
... and 5 more (see full listing online)

Locations (6 total)

The Royal Adelaide Hospital - Adelaide, SA,WA, Australia
Linear Clinical Research - Nedlands, SA,WA, Australia
Mackay Base Hospital - Mackay, SA,WA, Australia
... and 3 more locations