Low Dose Naltrexone for the induction of remission in patients with mild to moderate Crohn’s Disease that failed conventional treatment

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21939

Source
Nationaal Trial Register

Brief title
The LDN Crohn study

Health condition

Crohn's disease (CD)

Sponsors and support

Primary sponsor: ZonMW
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Endoscopic remission at week 12 defined as SES-CD ≤4 and ulcerated surface subscore ≤1 in

all five segments

Secondary outcome

- Proportion of patient in steroid free clinical remission
- Response defined by a decrease in HBI of ≥3 points compared to baseline and endoscopic response defined as a reduction of SES-CD score by ≥50% vs baseline at week 12
- Changes in laboratory measures of inflammation (CRP, fecal calprotectin) from baseline at week 12,24 and 52
- Adverse events at every visit
- Response at week 24 and 52 (HBI)
- Endoscopic remission and response at week 52
- Quality of life, fatigue, anxiety, depression, sleepdisturbance, healthcare costs, workdisability

Study description

Background summary

The aim of this study is to prospectively assess the efficacy of LDN as induction therapy in CD. In this multicentre, prospective, randomized, placebo-controlled study, patients with mild to moderate active CD will be randomized 1:1 to receive treatment with either LDN 4.5 mg or placebo for 12 weeks. After week 12 patients will be invited to participate in an open label exploratory extension study with visits at week 24, 36 and 52.

Study objective

The aim of this study is to prospectively assess the efficacy of LDN as induction therapy in CD.

Study design

Week 0, 2, 4, 8, 12, 24, 36, 52.

Intervention

LDN induction therapy 4.5 mg once daily or placebo orally for 12 weeks followed by open label maintenance therapy of 4.5 mg LDN once daily during one year.

Contacts

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Eligibility criteria

Inclusion criteria

- Age 18 or older; must have the ability to understand and sign a written ICF, which must be obtained prior to initiation of study procedures.
- Diagnosis of Crohn’s disease ≥3 months before screening.
- Objective evidence of inflammation at baseline as defined by endoscopy with mucosal ulcers in the ileum or colon or both, and a SES-CD score of 3-15.
- Concurrent therapies with stable doses of azathioprine, mercaptopurine, MTX or steroids (prednisolone ≤30 mg/dl or budesonide ≤9 mg per day) are permitted. Tapering of corticosteroids is mandatory.

Exclusion criteria

- Current use of i.v. corticosteroids.
- Imminent need for in-hospital treatment.
- Pregnancy or lactation.
- Previous or current treatment with investigational drug; current or past treatment within 6 months prior to randomization with a biological agent.
- Stool sample positive for Clostridium difficile (C. diff) toxin, pathogenic Escherichia coli (E. coli), Salmonella species (spp), Shigella spp, Campylobacter spp, or Yersinia spp.
- Other significant illnesses that may interfere with the study, stricture causing obstructive symptoms, or fistulising disease complicated by infection,
- Opiates use or drugs and/or alcohol abuse.
- Concomitant use of TNA alpha antagonist, Integrin antagonist, Interleukin antagonist, Cyclosporine, thalidomide, tacrolimus and any JAK inhibitors. Wash out period mandatory.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2020
Enrollment:	122
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
The data will be shared on reasonable request to the corresponding author.

Ethics review

Positive opinion

Date:	11-02-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9259
Other	METC Erasmus MC : MEC-2019-0602/NL69149.078.19

Study results