# Budenofalk granules and capsules in the treatment of Crohn's disease

No registrations found.

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|---|---|
| **Ethical review** | Not applicable |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON24660

**Source**
Nationaal Trial Register

**Brief title**
BALANCE

**Health condition**

Crohn's disease, budesonide, Budenofalk, IBD, ziekte van Crohn

### Sponsors and support

**Primary sponsor:** Dr. Falk Pharma Benelux B.V.
**Source(s) of monetary or material Support:** Dr. Falk Pharma Benelux B.V.

### Intervention

### Outcome measures

**Primary outcome**

The objective of this study is to obtain an insight into the treatment of acute Crohn’s disease with Budenofalk 9 mg granules and 3 mg capsules among outpatients attending regular gastroenterological practice. The primary outcome is the percentage of physicians who perform Budenofalk therapy as described in the SPC.

### Secondary outcome

Secondary objectives include therapeutic adherence, treatment success, tolerability and safety, ease of use and pharmacy substitution.

## Study description

### Background summary

European guidelines recommend 9 mg budesonide daily as the preferred initial therapy for mild to

moderate active Crohn’s disease localized at the ileocecal region. Existing guidelines do not provide

suggestions for the treatment schedule or duration, however. Though the SPCs for Budenofalk®

granules and Budenofalk® capsules provide guidance, treatment schedules using these agents are

generally formed by the treating physician in a case-by-case manner. Studies looking into the use of

Budenofalk® in this setting have not previously been performed. Likely, different dosing schedules and

treatment durations are employed for the induction of remission in Crohn’s disease patients in clinical

practice. We expect these differences could have an effect on several levels; e.g. therapeutic

adherence, success of therapy, patient experience, and drug tolerability.

This study has been developed to assess the use of Budenofalk® in the treatment of acute

Crohn’s disease in routine clinical practice We aim to assess how Budenofalk® is used; at which dose

and for how long, and how the observed differences impact the patient. Results obtained in this study

will help to improve the management of Crohn’s disease.

Approximately 150 adult patients, both male and female, with endoscopically determined

Crohn’s disease will be included. In accordance with the SPC, patients must be over 18 years of age at

the start of the therapy. The patients will belong to the regular outpatient population of the

participating physicians. They will be included in the study after an initial disease diagnosis or the

diagnosis of a new flare has been made and the treating physician has decided to prescribe

Budenofalk® 9 mg granules or 3 mg capsules. The prospective investigation will be carried out

throughout the Netherlands.

### Study objective

The purpose of this observational study is to obtain insight into the treatment of the acute phase of Crohn’s disease with Budenofalk® 9 mg granules and 3 mg capsules among outpatients attending regular gastroenterological practice. Likely, different dosing schedules and treatment durations are employed for the induction of remission. We aim to discover how these differences affect therapeutic adherence, success of therapy, patient experience, and drug tolerability.

### Study design

Treatment duration for each patient will be decided on by the treating physician and study visits will align with the regular consultations. The study will therefore include the initial consultation (day 0 of treatment), a follow up consultation after 2 - 5 weeks, a final consultation at the end of the therapy (i.e. after 6 - 10 weeks) and a follow up safety assessment (4 weeks post last treatment dose).

### Intervention

None. This is a prospective, multicenter, observational study. This means that intervention is not the purpose of this study; patients will be treated solely as part of regular medical therapy. Therapeutic necessity will be the only determinant of selection of the medicine.

## Contacts

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# Eligibility criteria

## Inclusion criteria

age > 18 years;

seen in the outpatient department;
have been prescribed Budenofalk granules or capsules for the treatment of mild to moderate active Crohn's disease;

have received adequate information regarding this observational study and have voluntarily agreed to the use of their data

## Exclusion criteria

have severe active Crohn's disease;

are being treated with corticosteroids for current flare;

are hypersensitive to the active substance or any of the excipients;

are enrolled and involved in an interventional study

# Study design

### Design

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|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-11-2016 |
| Enrollment: | 138 |
| Type: | Anticipated |

## Ethics review

Not applicable

| | |
|---|---|
| Application type: | Not applicable |

## 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 | NL5842 |
| NTR-old | NTR5997 |
| Other | Dr. Falk Pharma Benelux B.V. : BUG-004CDA |

## Study results