Improving adherence in ulcerative colitis (UC) patients on 5-ASA.

Published: 06-03-2014
Last updated: 15-05-2024

The aim of our study is to assess 1) The influence of once daily versus twice daily use of 5-ASA medication on adherence 2) The influence of the use of apps on adherence in ulcerative colitis patients on 5-ASA

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON40052

Source
ToetsingOnline

Brief title
Improving adherence in UC patients

Condition

- Gastrointestinal inflammatory conditions

Synonym
inflammatory bowel disease, ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,2 bedrijven,Shire,Tramedico

Intervention

Keyword: 5-ASA (5-aminosalicylates), adherence, mucosal healing, ulcerative colitis (UC)

Outcome measures

Primary outcome

Adherence measured as 5-ASA-metabolites in urine

Secondary outcome

1. quality of life

2. clinical as well as endoscopic remission

3. costs

4. safety

5. adherence as measured with questionnaires

in UC patients on 5-ASA

Study description

Background summary

5-ASA plays an important role in UC treatment guidelines and is recommended as induction of remission therapy for left sided colitis and mild-moderate extensive colitis. Medication adherence occurs when the patient carries out a therapy in the way in which it was intended by the treating physician. The reported prevalence of medication non-adherence varies from 40-91% in UC patients on 5-ASA and is comparable with those seen in other chronic illnesses. A high percentage of non-adherent patients who are at an increased risk for relapse is likely to contribute to higher costs associated with the treatment of UC. Our hypothesis is that once daily dosing and the use of interactive apps improves adherence in UC patients on 5-ASA.

Study objective

The aim of our study is to assess
1) The influence of once daily versus twice daily use of 5-ASA medication on adherence

2) The influence of the use of apps on adherence in ulcerative colitis patients on 5-ASA

Study design

This study is a randomized, controlled prospective multi-centre trial including 220 patients with ulcerative colitis. Patients will be randomly assigned to either once daily Mezavant® (2400 mg) or twice daily Mezavant® (2dd1200 mg), with a total follow up period of 18 months. Primary outcome is adherence, measured by presence of 5-ASA metabolites in urine at six months. Secondary outcomes are compliance measured by presence of 5-ASA metabolites in urine at 12 and 18 months. quality of life, clinical and endoscopic remission, costs and safety. Patients are randomised to either once daily 2400 mg Mezavant or twice daily 1200 mg Mezavant, and to either the standard treatment regime or assisted treatment regime with interactive apps on their mobile phone and/or ipad, with a total study follow up of 18 months. A sigmoidoscopy is performed at baseline, at the end of the study, or at withdrawal. Patients will be asked to visit the outpatient clinic or contact the IBD nurse via the app every 3-6 months, to collect urine and faeces samples, and to complete questionnaires regarding adherence (adherence questionnaire), clinical response, adverse events and health-related quality of life. Every six months blood samples are collected.

Intervention

Randomisation:
Once versus twice daily 5-ASA therapy to improve their compliance to 5ASA//Text messages and alerts via a specific app on their mobile phone versus standard of care to improve their compliance to 5ASA

Study burden and risks

The risk of participation in the current study is considered to be low compared to standard 5-ASA treatment outside this study protocol, since treatment in the study does not gradually differ from current practice. Patients in the intervention group may have a higher chance of reaching and maintaining clinical and endoscopic remission if suboptimal adherence can be increased by either once daily dosage or by assisted treatment regime with the use of apps. Patients have to bring some 3 additional visits to the hospital, or fill in an app. At entrance, and at the end of the study a sigmoidoscopy is performed. Every three months urine and faecal analysis have to be performed, at least every six months laboratory analysis. Next to this, patients will be asked to complete questionnaires on adherence, clinical remission and quality of life 6 times during treatment.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

geert grooteplein Zuid 10
Nijmegen 6525 GA
NL
Scientific
Universitair Medisch Centrum Sint Radboud

geert grooteplein Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age>18 and <80 years
Confirmed (clinical and histological) diagnosis of ulcerative colitis, either left sided or pancolitis (Montreal classification)
Patients in remission defined as a score of <5 SCCAI
5-ASA monotherapy or combination therapy with local therapy (suppositories/enemas/foam)
Patients in possession of mobile phone

Exclusion criteria

Pregnancy
Concomitant use of immunosuppressives

Use of immunosuppressives in the prior 3 months
No access to mobile phone

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-09-2014
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-04-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24807
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL39895.091.12
OMON	NL-OMON24807