Measuring 5-ASA urinary excretion levels in healthy volunteers

Published: 11-06-2013
Last updated: 26-04-2024

HPLC is feasible to assess the range of urinary 5-ASA excretion in healthy individuals using different dosages of oral 5-ASA, and HPLC is able to provide cut-off levels for (non-) compliance in persons using different dosages of 5-ASA tablets (...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36986

Source
ToetsingOnline

Brief title
Measuring 5-ASA urinary excretion

Condition

- Other condition

Synonym
urinary excretion 5-ASA

Health condition

pilot studie gezonde vrijwilligers

Research involving
Human

Sponsors and support

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

Intervention

Keyword: healthy volunteers, HPLC, pilot study, urinary 5-ASA

Outcome measures

Primary outcome

Primary outcome is the reproducibility and variability in the urinary 5-ASA excretion, as measured with HPLC, in healthy volunteers, and to establish urinary 5-ASA cut-off levels for adherence.

Secondary outcome

Secondary outcome is safety in terms of adverse events and rate of discontinuation due to adverse events of using 5-ASA. Daily morning urine samples will be collected and frozen at -20° before analysis.

Study description

Background summary

5-ASA plays an pivotal role in ulcerative colitis treatment guidelines. Medication adherence occurs when the patient carries out a therapy as intended by the treating physician. The reported prevalence of medication non-adherence varies from 40-91% in UC patients on 5-ASA, which leads to an increased risk for relapse. Therefore it is important to develop methods to improve patients adherence. The most objective way to study compliance, is to measure 5-ASA and its metabolite(s) in biological fluids as plasma or urine. Urinary 5-ASA excretion measurement by High performance Liquid Chromatography (HPLC) has been previously described. To be able to interpret urinary 5-ASA excretion levels in patients using 5-ASA, and to define urinary 5-ASA cut-off values as primary outcome for compliance, we need to study the range and variability of 5-ASA urinary excretion in healthy individuals.

Study objective

HPLC is feasible to assess the range of urinary 5-ASA excretion in healthy individuals using different dosages of oral 5-ASA, and HPLC is able to provide cut-off levels for (non-) compliance in persons using different dosages of 5-ASA tablets (Mezavant®).

Study design

This observational trial will include fifteen volunteers with a 14 week follow up period. All volunteers will follow a consecutive dosage schedule of 1200 mg 5-ASA once daily (OD), 2400 mg 5-ASA (OD) or 1200 mg twice daily (BD), 3600 mg (OD) or 1200 mg (OD) and 2400 mg (BD), and 4800 mg 5-ASA/day (OD) or 2400 mg (BD). All dosages will be used during 7 days, with a drug-free interval of 7 days in between dose adjustments. Entry criteria include the absence of significant co-morbidity or use of co-medication. Written informed consent will be obtained.

Intervention

In the 14 weeks study period, volunteers will receive 5-ASA tablets (Mezavant®) according to the study schedule either once-daily or twice daily. Daily morning urine spot samples will be obtained and stored at -20° prior to HPLC analysis. Volunteers will be called every week by the investigators to make sure that they take the medicine according to their prescribed schedule, and to question them on possible adverse events. Blood samples will be obtained at baseline, after 2 weeks of using 5-ASA and at end of the study

Study burden and risks

The risk of participation in the current study is considered to be low since 5-ASA treatment outside this study protocol is a widely accepted first-line treatment in IBD with few adverse events, and very small risk on a severe adverse event. For the exact information on the use of 5-ASA, an information brochure is added to this protocol. Healthy volunteers have to use 5-ASA medication during 7 weeks and have to collect daily urine spot samples in the morning. Every week they will be called by the investigators to make sure that they take the medicine according to their prescribed schedule, and to question them on possible adverse events. At baseline, after 2 weeks of using 5-ASA and at end of the study a blood sample is collected.

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 and no significant co morbidities or co-medication

Exclusion criteria

Pregnancy, significant co morbidities or co-medication, use of NSAIDs

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2012
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-06-2013
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL42016.091.12