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Urinary excretion levels of MMX-mesalazine in healthy volunteers

Submission date	Recruitment status	[ ] Prospectively registered
05/02/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/02/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/02/2015	Digestive System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Ulcerative colitis (UC) is a long-term condition where the colon (large intestine) and rectum is inflamed. Ulcers can develop in the lining of the affected region of the bowel, which can then bleed and produce pus. The severity of symptoms vary according to how much of the bowel is affected but include diarrhoea (with or without blood and pus), stomach pain and the urge to empty the bowels more frequently than normal. Sufferers may not have any symptoms, or only very mild symptoms, for long periods (remission) which can then be followed by periods where the symptoms are much more severe (flare-ups or relapses). There is no cure for the condition and treatment concentrates on alleviating symptoms. Medication is usually the first line of treatment. Patients commonly take aminosalicylates (ASA) including mesalazine. These drugs can be very successful in treating UC patients, but getting people to take them regularly can be a challenge. Here, we want to test if measuring (NAc) 5-ASA in the urine can be used to see whether people are taking their MMX-mesalazine (i.e. monitoring adherence).

Who can participate?
Healthy adult volunteers aged over 18.

What does the study involve?
Participants are given 2400 mg of MMX-mesalazine once a day for 4 days. They then stop taking the drug for 3 days. This is followed by them taking 1200 mg of MMX-mesalazine twice a day for a further 4 days. All participants are supervised when taking the drug to ensure full adherence. Daily urine spot samples are taken from each participant throughout the study before they take the medication.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Radboud University Nijmegen Medical Centre (Netherlands)

When is the study starting and how long is it expected to run for?
July 2013 to January 2014

Who is funding the study?
1. Shire (Ireland)
2. Tramedico (Netherlands)

Who is the main contact?
Dr Tessa Romkens

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
42016.091.12

Study information

Scientific Title
Urinary excretion levels of MMX-mesalazine in healthy volunteers: a non-randomised study

Study objectives
1. High-performance liquid chromatography (HPLC) is a feasible, sensitive and reproducible method to measure urinary (NAc-) 5-ASA excretion in volunteers taking MMX-mesalazine.
2. The (Nac)5-ASA urinary excretion cut-off-level for adherence was determined

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Radboud University Medical Center, Nijmegen, the Netherlands

Study design
25 healthy volunteers are studied during 14 days, using 2 different dosage schedules of MMX-mesalazine

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Urinary excretion MMX-mesalazine, pharmacokinetics. Now studied in healthy volunteers. To be used in inflammatory bowel disease (IBD) patients in the future.

Interventions
All 25 healthy adult volunteers used MMX-mesalazine (2400 mg once daily (OD) (days 1-4), followed by 1200 mg twice daily (BID) (days 8-11), separated by a drug-free interval of 3 days (days 5-7). Daily morning urine spot samples were collected prior to the morning dose.

Intervention Type
Drug

Drug/device/biological/vaccine name(s)
MMX-mesalazine

Primary outcome measure
1. Feasibility, sensitivity, and reproducibility of high-performance liquid chromatography (HPLC) to measure urinary (NAc-) 5-ASA excretion in healthy volunteers taking MMX mesalazine
2. Adherence: The cut-off-level for adherence was defined as the total (Nac)5-ASA urinary excretion level, as measured in at least 95% of the subjects, taking 2400 mg MMX-mesalazine OD or BID

Secondary outcome measures
Adverse events

Overall study start date
24/07/2013

Completion date
13/01/2014

Eligibility

Key inclusion criteria
1. > 18 years
2. No comorbidity
3. No relevant co-medication especially NSAIDs or aspirin
4. Not pregnant

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25

Key exclusion criteria
1. Pregnancy
2. Relevant co-morbidity
3. Relevant co-medication

Date of first enrolment
24/07/2013

Date of final enrolment
11/11/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
Radboud University Nijmegen Medical Centre
Geert Grooteplein-Zuid 10
Nijmegen
Netherlands
6525 GA

Sponsor information

Organisation
Radboud University Nijmegen Medical Centre

Sponsor details
P.O. Box 9101
Nijmegen
Netherlands
6500 HB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Industry

Funder Name
Shire

Alternative Name(s)
Shire Pharmaceuticals

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Ireland

Funder Name
Tramedico (Netherlands)

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request