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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
Dr Tessa Romkens

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# Additional identifiers

### Protocol serial number
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

### Primary study design
Interventional

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

### Study type(s)
Treatment

### 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(s)
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

### Key secondary outcome(s)
Adverse events

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

**Sex**
All

**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

**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

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Available on request