Aspirin provocation of patients with Systemic Mastocytosis

Published: 06-07-2016
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To determine the prevalence and severity of ASA-related allergic reaction in SM patients.

Ethical review	Not approved
Status	Will not start
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON43428

Source
ToetsingOnline

Brief title
Provocation trial

Condition

- Allergic conditions

Synonym
Allergy; systemic mastocytosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anaphylaxis, Aspirin, NSAID, Systemic Mastocytosis

Outcome measures

Primary outcome

- frequency of allergic reactions due to ASA ingestion

- severity of anaphylaxis: grading of symptoms

Secondary outcome

- measurment of mast cell mediators before and after ASA ingestion; serum

trypase levels, plasma 11bèta-PGF2a levels, urine leukotriene E4 levels and

urine N-methylhistamine levels.

- daily SM-related symptoms: information will be retrieved with questionnaires.

- measurement of health-related quality of life of SM patients.

Study description

Background summary

Systemic mastocytosis (SM) is a myeloproliferative disease in which aberrant mast cells accumulate. Patients with SM experience more anaphylaxis than healthy persons because of the large amount of mast cells. For this reason, the use of certain medications that theoretically could trigger mast cell degranulation is discouraged in SM patients. Among these medications are radiologic contrast media, anaesthetics, opioid analgesics and nonsteroidal anti-inflammatory drugs (NSAID*s). However, SM patients could benefit from some of these drugs in their daily life. Acetylsalicyl acid (ASA) is a proven remedy for flushing in some patients. Moreover, since osteoporosis is a frequent complication of SM, they are more often in need of analgesics due to fractures etc. Officially, the only *allowed* analgesic is acetaminophen. For these reasons, it would be of great importance to explore the real prevalence and severity of aspirin-induced anaphylaxis in SM patients. Aspirin can be used as a model for all NSAID*s.
Please see the complete procotol for a more extensive review of the literature.

Study objective

To determine the prevalence and severity of ASA-related allergic reaction in SM

patients.

Study design

Double-blind, placebo-controlled intervention study.

Intervention

Provocation with ASA
1 day of 4 hours, patients will receive three placebo tablets
1 day of 4 hours, subjects will receive ASA in three ascending dosages

Study burden and risks

Patients will have to spend 2 separate days of 4 hours in the hospital. During these days, we will collect blood and urine samples on two occasions. Questionnaires and minor physical examination will be performed every hour to screen for anaphylactic symptoms.
We do not expect the patients to experience any other discomfort. However, they will be at theoretical risk for anaphylaxis during the provocation test. We expect a low incidence and minor severity of anaphylactic symptoms. However, a medical doctor and trained nursing staff will be available at all times to monitor symptoms and treat anaphylaxis if necessary. Facilities for admittance of patients for longer observation is available if necessary.
As argumented before in this protocol, participation in this study has direct benefit for subjects; they will be informerd whether they can safely use NSAID's in the future. ASA can be used to treat flushing, a symptom that has large influence on their quality of life. Secondly, up to 40% of SM patients develop osteoporosis which can be accompanied by pain, which can be treated with NSAID's.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Systemic mastocytosis, according to WHO criteria.

Exclusion criteria

Severe of uncontrolled asthma (FEV1<70%), nasal polyps, chronic rhinosinusitis, previous anaphylaxis due to NSAID's, patients who are not able to provide follow-up information, patients who are not deemed capable of handling possible delayed anaphylaxis at home.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-08-2016
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	acetylsalicylic acid APOTEX CARDIO 80 mg
Generic name:	acetylsalicylic acid
Registration:	Yes - NL intended use

Ethics review

Not approved

Date:	06-07-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2015-004604-37-NL
CCMO	NL55891.078.16