Aspirin provocation of patients with Systemic Mastocytosis

Published: 16-02-2017
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To determine the prevalence and severity of aspirin-related allergic reactions in SM patients.

Ethical review	Approved WMO
Status	Pending
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON45671

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: acetylsalicylic acid, anaphylaxis, Mastocytosis, NSAID

Outcome measures

Primary outcome

The frequency and severity of allergic reactions to aspirin.

Secondary outcome

- the influence of aspirin on mast cell mediators; e.g. measurement of serum

tryptase and 11bèta-PGF2 levels and of urine leukotriene E4 and

N-methylhistamine levels

- daily SM-related symptoms and quality of life (questionnaires)

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 could theoretically 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 widely-used remedy for flushing in some patients. Moreover, since osteoporosis is a frequent complication of SM with up to 50% having reduced bone density[5], they are more often in need of analgesics due to fractures etc. Lastly, SM patients are at increased risk for cardiovascular morbidity and of course, aspirin is the cornerstone of (secondary) prophylaxis for these diseases.
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.

Study objective

To determine the prevalence and severity of aspirin-related allergic reactions in SM patients.

Study design

Double-blind, placebo-controlled, crossover study.

Intervention

Double blind, placebo controlled provocation with aspirin.

Study burden and risks

Patients will have to spend 2 half days of approximately 4 hours in the hospital in which they will be asked to take three tablets (either placebo or ASA). 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. We expect a low incidence and minor severity of allergic symptoms.

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:	Pending
Start date (anticipated):	01-01-2017
Enrollment:	91
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

Approved WMO Date:	16-02-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-02-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-04-2017
Application type:	Amendment
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	NL59263.078.16