A study to evaluate the response of whole blood stimulation with lipopolysaccharide or other inducers and its in vitro inhibition in healthy volunteers, and patients with a chronic inflammatory condition

Published: 22-04-2008
Last updated: 18-07-2024

At CHDR, experience has been gained with the assessment of the in vitro inhibition by MAP kinases of the LPS-induced TNFα release in healthy male volunteers. However, relatively little is known on the inhibition by MAP-kinases in other populations....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON38316

Source
ToetsingOnline

Brief title
LPS-pilot healthy volunteers/patients

Condition

- Coronary artery disorders
- Autoimmune disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerose, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: CHDR

Intervention

Keyword: inflammation, MAPkinase inhibition, rheumatoid arthritis, whole blood

Outcome measures

Primary outcome

activation markers of inflammation (cytokines, chemokines, etc)

Secondary outcome

n/a

Study description

Background summary

Anti-inflammatory therapy is pursued as an approach to treatment for inflammatory diseases such as rheumatoid arthritis, Crohn*s disease and psoriasis. Rational development of such compounds would be facilitated when the possible variability in response in different target populations is known. The response to MAP-kinase inhibition can be assessed using the LPS whole blood stimulation test. Additional inducers can be used in this study.

Study objective

At CHDR, experience has been gained with the assessment of the in vitro inhibition by MAP kinases of the LPS-induced TNFα release in healthy male volunteers. However, relatively little is known on the inhibition by MAP-kinases in other populations. This is not trivial as there are indications that gender and disease state may have a substantial influence on the inhibition. In the whole blood stimulation test also other anti-inflammatory compound can be used.
In addition, technical advances enable to evaluate the response of more cytokines simultaneously using the Biochip Array Technology and the so-called

Multiplex technology.

The objective of this study is to explore the characteristics of the whole blood LPS-stimulation test or other inducers and its in vitro inhibition in healthy volunteers, and patients with Crohn*s disease, asthma, psoriasis rheumatoid arthritis, or proven atherosclerotic disease

Study design

Open, observational study with 90 participants. From each patient a single blood draw will be taken.

Study burden and risks

n/a

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

healthy males
healthy female volunteers: pre- and post-menopausal
patients with rheumatoid arthritis: active disease and with or without treatment with MTX
patients with Crohn's disease: clinically confirmed diagnosis of disease
patients with psoriasis: clinically confirmed diagnosis of disease, PASI score>5
patients with asthma: clinically confirmed diagnosis of disease
patients with proven atherosclerotic disease

Exclusion criteria

general: any clinically significant disorder (current or past medical history or physical examination) that in the opinion of the investigator precludes study participation
patients: clinically significant abnormalities and recent treatment with anti-TNF therapy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-09-2008
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL21958.058.08