Metabolic adverse events before and after glucocorticoid pulse therapy in rheumatoid arthritis

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1. Standardized reporting of occurrence of metabolic adverse events after treatment with glucocorticoid pulse therapy in chronic rheumatoid arthritis patients (who have exacerbation of disease).2. Determing if metabolic adverse events due to...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON35669

Source
ToetsingOnline

Brief title
Risks of glucocorticoid pulse therapy in rheumatoid arthritis

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Autoimmune disorders
- Joint disorders

Synonym
rheumatic disease, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Top Institute Pharma (TIP). TIP is een samenwerkingsverband tussen industrie en academische onderzoeksteams. Afdeling Reumatologie van het UMCU participeert in project T1-106 'glucocorticoid-induced insulin resistance'.

Intervention

Keyword: glucocorticoids, metabolic adverse events, rheumatic diseases

Outcome measures

Primary outcome

Metabolic disturbances

-Physical examination: weight, blood pressure

-Laboratory examination: fasting lab with a.o. an OGTT and lipid profile

Secondary outcome

Disease activity

-Interview:

oVisual Analogue Scale (VAS)-pain, VAS-well being

-Physical examination:

oTender joint score

oSwollen joint score

-Laboratory examination:

oFasting with a.o. ESR and hemoglobin

Cardiovascular risk factors

-Interview:

Smoking, alcohol use, diabetes (family history), lipid disorder, hypertension,

cardiovascular disease (family history, events), sports/activities (with

questionnaire Short QUestionnaire to ASses Health enhancing physical activity).

-Physical examination:

Waist- en hip circumference, ankle-arm index with Doppler machine.

Study description

Background summary

Since the discovery of glucocorticoids and their efficacy by Philip Hench in 1948, this medication is often used in rheumatoid arthritis. Nevertheless, the balance between risks and benefits is unclear and the exact place for glucocorticoids in treating rheumatoid arthritis unknown. Most of the adverse events (risks) seem to be dose-dependant and are not a serious risk in treatment with low-dose glucocorticoids (below or equal to 7.5 mg prednisone). In high-dose therapy, such a pulse therapy, we see these adverse events more often (for example: increase in blood pressure, glycosuria etc.). Nevertheless, the occurrence of these adverse events is not clearly described until now. Therefore, we want to study the occurrence of adverse events.

Study objective

1. Standardized reporting of occurrence of metabolic adverse events after treatment with glucocorticoid pulse therapy in chronic rheumatoid arthritis patients (who have exacerbation of disease).
2. Determing if metabolic adverse events due to glucocorticoid pulse therapy are transient or persistent.
3. Investigate whether non-responders to glucocorticoid pulse therapy suffer from less metabolic adverse events than responders.

Study design

-Longitudinal
-Monitoring: 3 research-visits of 2.5 hours (2 visitis during the hospital stay (day 1 and 6) and one visit six weeks later.

Procedure:
-Patients are studied in fasting condition (therefore, the measurements are performed in the morning). A 2-hours oral glucose tolerance test (OGTT) is performed and blood will be taken for laboratory analyses. In total, 60 mL will be drawn. Moreover, urine is collected. During the OGTT an interview will be taken (partly with help of questionnaires) and physical examination will be

performed.

Study burden and risks

The study consists of three visits. Two times patients participate during their hospital stay. A third time (six weeks later), they visit for the last measurements. Patients are asked to remain fasting until blood is drawn.

There are no specific risks involved. A hematoma can develop at the location of the vene used for blood drawing.

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

Rheumatoid arthritis exacerbation, defined by Disease Activity Score of 5.1 or higher.

Exclusion criteria

Patients with diabetes
Patients with clinical contra-indication for pulse therapy
Patients with DMARD changes during the last month

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	dexamethasone
Generic name:	dexamethasone
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	08-03-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-07-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	EUCTR2009-017051-10-NL
Other	Na goedkeuring door de METC zal de studie worden geregistreerd in het trialregister.
CCMO	NL29727.041.09