ISRCTN53261020 https://doi.org/10.1186/ISRCTN53261020

Top Institute Pharma (TIP)-glucocorticoids research University Medical Centre Utrect (UMCU) rheumatology: cardiovascular risk factors and insulin resistancy in rheumatoid arthritis patients with and without glucocorticoids

Submission date
23/08/2007

Recruitment status
No longer recruiting

Registration date
23/08/2007

Overall study status
Completed

Last Edited
17/10/2008

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR1028

Study information

Scientific Title

Acronym
TIP-GC-UMCU

Study objectives
What is the relation between disease activity, treatment, and metabolic syndrome/insulin resistance?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending from the METC UMC-Utrecht (The Netherlands) as of 31st August 2007.

Study design
Observational clinical trial

Primary study design
Observational

Secondary study design
Single-centre

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Insulin resistancy in rheumatoid arthritis patients

Interventions
1. Oral glucose tolerance test (OGTT)
2. X-rays of hand, feet, lungs and spinal cord
3. Electrocardiogram (ECG)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Metabolic syndrome/insulin resistance
2. Disease (RA) activity

Timepoints will be measured during a one time visit of the patient (duration approximately four hours).

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/10/2007

Completion date
01/10/2010

Eligibility

Key inclusion criteria
Diagnosis rheumatoid arthritis with disease duration greater than two years

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
300

Key exclusion criteria
Does not comply with the above inclusion criteria

Date of first enrolment
01/10/2007

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Utrecht
Utrecht
Netherlands
3584 RD

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (The Netherlands)

Sponsor details
Department of Rheumatology and Clinical Immunology
P.O. Box 85500
Utrecht
Netherlands
3508 GA

Sponsor type
Hospital/treatment centre

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Industry

Funder Name
Top Institute Pharma (TIPharma) (The Netherlands)

Alternative Name(s)
TI Pharma

Funding Body Type

Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration