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A randomised controlled trial evaluating the effects of long-term low-dose corticosteroid therapy compared to placebo on flare rates during maintenance therapy for proliferative lupus nephritis: a pilot study

Submission date
18/09/2006

Registration date
12/10/2006

Last Edited
28/03/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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
18864

Study information

Scientific Title
A randomised controlled trial evaluating the effects of long-term low-dose corticosteroid therapy compared to placebo on flare rates during maintenance therapy for proliferative lupus nephritis: a pilot study

Acronym
SIMPL

Study objectives
Comparison of flare of lupus rates in patients randomised to low-dose corticosteroids to those randomised to corticosteroid discontinuation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Calgary Conjoint Medical Ethics Committee (Canada)

Study design
Blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Systemic lupus erythematosus and lupus nephritis

Interventions
Prednisone/Prednisilone 7.5 mg versus placebo

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Corticosteroids

Primary outcome measure
Time to flare of SLE

Secondary outcome measures
1. Time to renal flare
2. Differences in quality of life as measured by Short Form - 36 and Euroquol 5D instrument
3. Differences in disease activity as measured by British Isles Lupus Activity Grade and Systemic Lupus Erythematosus Activity Index
4. Differences in disease damage as measured by the Systemic Lupus International Collaborative Clinics/American College of Rheumatology (SLICC/ACR) damage score
5. Differences in steroid-related adverse events

Overall study start date
30/09/2006

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. American College of Rheumatology defined systemic lupus erythematosus
3. International Society of Nephrology/Renal Pathology Society (ISN/RPS) class III or IV lupus nephritis on last renal biopsy
4. In complete or partial remission
5. Currently on corticosteroids
6. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Receiving steroids for a non-Systemic Lupus Erythematosus (SLE) indication
2. Currently pregnant
3. On a form of renal replacement therapy or having received a renal transplantation

Date of first enrolment
30/09/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Canada

United Kingdom

Study participating centre
Foothills Hospital
Calgary
Canada
T2N 2T9

Sponsor information

Organisation
University of Calgary (Canada)

Sponsor details
3330 Hospital Drive NW
Calgary
Canada
T2N 4N1

Sponsor type
University/education

Website
http://www.ucalgary.ca/

ROR

https://ror.org/03yjb2x39

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Centre for Advancement of Health (Canada)

Funder Name
Division of Nephrology (Canada)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/11/2014		Yes	No