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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

Contact name
Dr Braden Manns

Contact details
Division of Nephrology
Foothills Hospital
1403-29th St NW
Calgary
Canada
T2N 2T9
+1 (0)403 944 1110
Braden.Manns@CalgaryHealthRegion.ca

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Time to flare of SLE

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

Canada

Study participating centre
Foothills Hospital
Calgary
Canada
T2N 2T9

Sponsor information

Organisation
University of Calgary (Canada)

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

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				

Results article	28/11/2014	Yes	No