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The role of steroids in infection-related glomerulonephritis

Submission date
08/02/2021

Recruitment status
No longer recruiting

Registration date
28/02/2021

Overall study status
Completed

Last Edited
22/02/2021

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Infection-related glomerulonephritis is inflammation of the tiny filters in the kidneys (glomeruli) caused by infection. Given the role of immune activation in the disease, there has been interest in the use of immunosuppression to improve clinical outcomes. The aim of this study is to find out whether the use of steroids can improve renal (kidney) outcomes in patients with infection-related glomerulonephritis.

Who can participate?
Patients aged over 18 with infection-related glomerulonephritis

What does the study involve?
Participants are randomly allocated to receive either standard care or standard care plus corticosteroids. Participants allocated to corticosteroids are given intravenous methylprednisolone (into a vein) on 3 consecutive days, followed by oral prednisolone for 1 month, followed by a slow taper at 5 mg/week. Disease remission is assessed after 6 months, or at the time of the last follow-up, whichever is earlier.

What are the possible benefits and risks of participating?
The use of corticosteroids may improve renal outcomes in patients with infection-related glomerulonephritis. There is a potential risk of steroid toxicity.

Where is the study run from?
Institute of Nephrology, Rajiv Gandhi Government General Hospital (India)

When is the study starting and how long is it expected to run for?
April 2016 to December 2021

Who is funding the study?
Madras Medical College (India)

Who is the main contact?
Dr Tanuj Moses Lamech
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A randomized controlled trial of corticosteroids in infection-related glomerulonephritis

Study objectives
Infection-related glomerulonephritis is an immune-complex disease. This study tests the hypothesis that steroids ameliorate the deleterious consequences of immunological activation, and improve outcomes in patients with infection-related glomerulonephritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/09/2017, Institutional Ethics Committee, Madras Medical College (Madras Medical College, EVR Periyar Salai, Park Town, Chennai 600 003, India; Telephone number: +91 (0)44 25363970; ethicsmmc@gmail.com), ref: 18092017

Study design

Open-label single-centre randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Infection-related glomerulonephritis

Interventions
Patients meeting the inclusion criteria are randomized 1:1, in blocks of 4, to receive either standard care (control arm), or standard care plus corticosteroids (intervention arm). Patients randomized to the intervention arm are given pulses of intravenous methylprednisolone (1 g) on 3 consecutive days. This is followed by oral prednisolone 1 mg/kg/day for 1 month, followed by a slow taper at 5 mg/week. No matching placebo was provided to the control arm, and the trial was open-label.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Methylprednisolone, prednisolone

Primary outcome(s)
Complete remission, defined as an estimated glomerular filtration rate (eGFR) of >60 ml/min/1.73m², assessed at 6 months after randomisation, or at time of last follow-up, whichever is earlier

Key secondary outcome(s))
1. Combined complete remission (defined as eGFR >60 mL/min/1.73m² at 6 months) and partial remission (defined as serum creatinine lower than peak creatinine during initial admission, along with eGFR <60 mL/min/1.73m² at 6 months)
2. Death and end-stage renal disease (taken from the patient's medical records) at 6 months
3. Persistent proteinuria (urine PCR >0.5 or dipstick 2+ or more) at 6 months
4. Dialysis independence at any point within 6 months since randomization, among patients with dialysis-requiring renal failure at initial presentation (taken from the patient's medical records)

Completion date
30/11/2020

Eligibility

Key inclusion criteria
1. Patients older than 18 years who provide written informed consent
2. Fulfilment of 3/5 of the Nasr et al. criteria for infection-related glomerulonephritis
3. Serum creatinine >1.5 mg/dl at time of randomisation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
86

Key exclusion criteria
1. More than 21 days elapsed since presentation
2. Presence of a contraindication for steroids
3. Seropositivity for HIV, hepatitis B, or hepatitis C
4. Hypocomplementaemia at 3 months
5. IgA-dominant infection-related glomerulonephritis
6. Crescents involving >50% of the sampled glomeruli
7. Diabetic nephropathy class III or IV
8. Interstitial fibrosis and tubular atrophy >40%

Date of first enrolment
06/09/2017

Date of final enrolment
31/05/2020

Locations

Countries of recruitment
India

Study participating centre
Rajiv Gandhi Government General Hospital
Park Town
Chennai
India
600 003

Sponsor information

Organisation
Madras Medical College

ROR
https://ror.org/050ztxn78

Funder(s)

Funder type
University/education

Funder Name
Madras Medical College

Results and Publications

Individual participant data (IPD) sharing plan
Data not available due to ethical/legal restrictions

IPD sharing plan summary
Not expected to be made available