

Immunosuppression for progressive membranous nephropathy

Submission date 25/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/10/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 01/02/2013	Condition category Urological and Genital Diseases	<input type="checkbox"/> 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
G9721265

Study information

Scientific Title

Study objectives

To test whether immunosuppression alters the natural history of progressive membranous glomerulonephritis and to compare two types of immunosuppressive treatment: cyclosporin and prednisolone/chlorambucil

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Multi-centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Progressive membranous glomerulonephritis

Interventions

Randomisation will be between three groups:

1. One receiving supportive treatment only
2. One receiving 12 months treatment with cyclosporin
3. One receiving six months treatment with a combination of prednisolone and chlorambucil

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cyclosporin and prednisolone/chlorambucil

Primary outcome measure

Glomerular filtration rate with a further decline of 20% being an end-point

Secondary outcome measures

Proteinuria and adverse effects

Overall study start date

15/01/1999

Completion date

31/03/2009

Eligibility

Key inclusion criteria

1. Idiopathic membranous nephropathy with a 20% decline in glomerular filtration rate
2. Patients aged between 18 and 75

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

120 (40 in each group), interim follow-up at 2 years, final follow-up at 5 years. Added 23/09/09:
Closed to recruitment, 108 recruited, in follow-up.

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

15/01/1999

Date of final enrolment

31/03/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Academic Renal Unit
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
University of Bristol (UK)

Sponsor details
Senate House
Tyndall Avenue
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England
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BS8 1TH
+44 (0)117 928 9000

Sponsor type
University/education

Website
<http://www.bris.ac.uk/>

ROR
<https://ror.org/0524sp257>

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	02/03/2013		Yes	No