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Immunosuppression for progressive membranous nephropathy

Submission date	Recruitment status	[_] Prospectively registered
25/10/2000	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2000	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/02/2013	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Professor Peter Mathieson

Contact details
Academic Renal Unit
University of Bristol
Southmead Hospital
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

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
Proteinurea 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
Bristol
England
United Kingdom
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