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Treatment with adrenocorticotropic hormone in idiopathic membranous nephropathy

Submission date	Recruitment status	[ ] Prospectively registered
06/12/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/01/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/01/2007	Urological and Genital Diseases	[ ] Record updated in last year

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
N/A

Study information

Scientific Title

Study objectives
Idiopathic membranous nephropathy is one of the most common causes of the nephrotic syndrome in adults. It leads to end-stage renal disease in roughly half of the patients. The disease is characterised by glomerular, subepithelial deposits which consist of immune complexes.

The hypothesis was that treatment with Adrenocorticotropic Hormone (ACTH) is superior to no specific treatment in nephrotic patients with idiopathic membranous nephropathy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was accepted by the Ethics Committees in Lund, Sweden (ref: LU 183-99) and Gothenburg, Sweden (ref: Gbg M056-99). The date of final acceptance was May 18, 1999.

Study design
Prospective, randomised, controlled, open-label interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Idiopathic membranous nephropathy

Interventions
The participants were randomised to treatment with Synacthen Depot or no specific treatment. Synacthen Depot is a depot preparation of a synthetic fragment of ACTH. The fragment consists of the first 24 amino acids of the native human peptide and it retains the adrenal activity. ACTH is formed in the pituitary gland. Its main action is the stimulation of the production/secretion of cortisol. The cortisol released by the actual dose of Synacthen Depot is not enough to explain an effect on membranous nephropathy. Thus, the mechanism of such an effect is unknown.

The dosage scheme of Synacthen Depot given subcutaneously was as follows:
Month one: 1.0 mg once a week
Month two: 0.75 mg twice a week
Months three to six: 1.0 mg twice a week
Month seven: 0.75 mg twice a week
Month eight: 1.0 mg once a week
Month nine: 0.5 mg once a week

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Adrenocorticotropic Hormone (ACTH) in the form of Synacthen Depot

Primary outcome measure
The primary outcomes were complete remissions and the combination of complete and partial remissions at the end of the treatment period (nine months after study start) and at the end of the follow-up period (21 months after study start).

A complete remission was defined as urinary albumin excretion less than 200 mg/24 hours and a partial remission was defined as urinary albumin excretion less than 2000 mg/24 hours in combination with a reduction of at least 50%.

Secondary outcome measures
The secondary outcomes were the changes at the end of the treatment period and the end of the follow-up period, as compared to baseline, in the serum concentrations of albumin, creatinine, apolipoprotein A1, apolipoprotein B and lipoprotein(a), the urinary excretion/24 hours of albumin, immunoglobulin G and protein HC, glomerular filtration rate and mean arterial pressure.

Overall study start date
06/07/1999

Completion date
31/01/2005

Eligibility

Key inclusion criteria
1. Males and females
2. Age 18 to 90
3. Membranous nephropathy according to kidney biopsy
4. Proteinuria of the nephrotic range for at least six months
5. Treatment with a statin and an angiotensin converting enzyme inhibitor for at least three

months
6. Urinary albumin excretion more than 3000 mg/24 hours
7. Serum albumin concentration less than 26 g/L

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Thirty

Key exclusion criteria
1. Moderate or heavy tubulointerstitial changes in the kidney biopsy
2. A recognisable cause of the nephrotic syndrome
3. Previous immunosuppressive treatment for the membranous nephropathy
4. Allergy to Synacthen Depot
5. Severe psychiatric disease
6. Pregnancy
7. History of noncompliance

Date of first enrolment
06/07/1999

Date of final enrolment
31/01/2005

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Nephrology
Lund
Sweden
221 00

Sponsor information

Organisation
Department of Nephrology, University Hospital in Lund (Sweden)

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Sponsor type
Hospital/treatment centre

Website
http://www.skane.se/templates/Page.aspx?id=109334

ROR
https://ror.org/012a77v79

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Department of Medicine of the University in Lund (Sweden) (ref: M: B 39 422/01, M: B 19 1036/03, M: B 1002/04)

Funder Name
The Federation of Swedish County Councils, Region Skane (Sweden) (ref: Lf 1297/00)

Funder Name
The Department of Nephrology, University Hospital in Lund (Sweden)

Funder Name
The Department of Nephrology, Sahlgren´s University Hospital, Gothenburg (Sweden)

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