

Treatment with adrenocorticotrophic hormone in idiopathic membranous nephropathy

Submission date 06/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/01/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/01/2007	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 Adrenocorticotrophic 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)

Adrenocorticotrophic 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)

Sponsor details

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+46 (0) 46 17 12 47

kerstin.wihlborg@med.lu.se

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