

# Treatment with adrenocorticotrophic hormone in idiopathic membranous nephropathy

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<b>Registration date</b> 26/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/01/2007	<b>Condition category</b> 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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**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