Clinical trial results:
Treatment of primary minimal change nephropathy.
A randomized, open-labeled, non-inferiotiry study on prednisolone and vitamin D

Summary

EudraCT number	2017-001206-16
Trial protocol	DK
Global end of trial date	21 January 2025

Results information

Result version number	v1 (current)
This version publication date	10 July 2025
First version publication date	10 July 2025

Trial information

Trial identification

Sponsor protocol code	121934

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03210688
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Palle Juul-Jensens Boulevard, Aarhus, Denmark, 8200
Public contact	Per Ivarsen, Nyresygdomme, Aarhus University hospital, perivars@rm.dk
Scientific contact	Per Ivarsen, Nyresygdomme, Aarhus University hospital, perivars@rm.dk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	21 January 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 January 2025
Global end of trial reached?	Yes
Global end of trial date	21 January 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective is to se if lowers dose of prednisolone combined with vitamin D can give the same results in clearing the disease, but give the patients fewer side effects.
We compare high dose prednisolone to low dose prednisolone cmbined with vitamin D, and we predict that the regimens are non-inferior and give the same results on the disease, but fewer side effects when prednisolone are reduced.

Protection of trial subjects:

The study is performed in accordance with the Declaration of Helsinki and has been approved by The Danish Data Protection Agency (record no.: 1-16-02-38-17), The Danish Medicines Agency (record no.: 2017-001206-16), and the Research Ethics Committees (record no.: 1-10-72-178-17). The study is monitored by the Good Clinical Practice (GCP) units in Aarhus and Aalborg, Copenhagen, and Odense. The data management respects the Danish Data protection Agency law on data protection and all data are stored in RedCap which is a secure web application for building and managing online databases and surveys. Sponsor and principle investigator have access to all data, but local investigators only have access to data on local participants.
The lower prednisolone dose in one intervention arm implies a risk of delayed remission; however, the potential benefits resulting from the possibility that a lower dose of prednisolone with reduced adverse effects with similar efficacy as high dose prednisolone should outweigh this risk. No patients will receive higher dose of prednisolone than currently used clinical practice. Alfacalcidol is unlikely to cause symptoms; however, may induce hypercalcemia. The risk associated with this is considered minimal since plasma levels of ionized calcium are monitored throughout the trial and alfacalcidol will be reduced or stop as appropriate.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 September 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 67
Worldwide total number of subjects	67
EEA total number of subjects	67

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	51
From 65 to 84 years	15
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

patients will be recruited from all renal departments in Denmark by collaborative partners who already has given consent to participate.

Pre-assignment

Screening details:

Inclusion criteria: Kidney biopsy proven minimal change disease, age > 18 years, nephrotic syndrome at presentation

Pre-assignment period milestones

Number of subjects started	67
Number of subjects completed	67

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Intervention

Arm description:

Lower dose prednisolone and alfacalcidol

Arm type	Experimental
Investigational medicinal product name	prednisolone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

0.5 mg/kg/day

Investigational medicinal product name	Alfacalcidol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

0.5 mikrogram/day

Arm title	Standard

Arm description:

Standard prednisolone according to guidelines

Arm type	Active comparator

Investigational medicinal product name	prednisolone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg/kg/day

Number of subjects in period 1	Intervention	Standard
Started	33	34
Completed	33	34

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	67	67	
Age categorical Units: Subjects			
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	51	51	
From 65-84 years	15	15	
85 years and over	1	1	
Gender categorical Units: Subjects			
Female	30	30	
Male	37	37	

End points

End points reporting groups

Reporting group title	Intervention
Reporting group description: Lower dose prednisolone and alfacalcidol	
Reporting group title	Standard
Reporting group description: Standard prednisolone according to guidelines	

Primary: Remission

End point title	Remission
End point description:	
End point type	Primary
End point timeframe: within 16 weeks	

End point values	Intervention	Standard		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	34		
Units: albuminuria				
number (not applicable)				
Remission	29	31		
no remission	4	3		

Statistical analyses

Statistical analysis title	Primary outcome
Comparison groups	Intervention v Standard
Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.05
Method	Mantel-Haenszel

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From inclusion to end of study	
Adverse event reporting additional description:	
Blood test, urine test and quiestionarries	
Assessment type	Systematic

Dictionary used	
Dictionary name	None
Dictionary version	0

Reporting groups	
Reporting group title	Standard
Reporting group description:	
High dose prednisolone	
Reporting group title	Intervention
Reporting group description:	
Lower dose prednisolone + alfacalcidol	

Serious adverse events	Standard	Intervention	
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 34 (20.59%)	0 / 33 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Vascular disorders			
Lung embolia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 33 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
SAE related to psychiatric disease			
subjects affected / exposed	2 / 34 (5.88%)	0 / 33 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
SAE related to infections			
subjects affected / exposed	4 / 34 (11.76%)	0 / 33 (0.00%)	
occurrences causally related to treatment / all	4 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Standard	Intervention	
Total subjects affected by non-serious adverse events subjects affected / exposed	34 / 34 (100.00%)	17 / 33 (51.52%)	
Nervous system disorders Unspecified pain subjects affected / exposed occurrences (all)	18 / 34 (52.94%) 18	8 / 33 (24.24%) 8	
Gastrointestinal disorders Increased appetite subjects affected / exposed occurrences (all)	10 / 34 (29.41%) 10	3 / 33 (9.09%) 3	
Endocrine disorders Moon face subjects affected / exposed occurrences (all)	13 / 34 (38.24%) 13	6 / 33 (18.18%) 6	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported