



Clinical trial results:

Treatment of primary minimal change nephropathy.

A randomized, open-labeled, non-inferiortiry 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 see 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 combined 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 questionnaires

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

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|-----------------|------|
| 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 | 18 / 34 (52.94%) | 8 / 33 (24.24%) | |
| occurrences (all) | 18 | 8 | |
| Gastrointestinal disorders | | | |
| Increased appetite | | | |
| subjects affected / exposed | 10 / 34 (29.41%) | 3 / 33 (9.09%) | |
| occurrences (all) | 10 | 3 | |
| Endocrine disorders | | | |
| Moon face | | | |
| subjects affected / exposed | 13 / 34 (38.24%) | 6 / 33 (18.18%) | |
| occurrences (all) | 13 | 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