# Clinical trial results:
# Effect of high versus low dose intravenous dexamethason on complications in the immediate postoperative setting after nephrectomy- a randomized, double-blind, controlled trial

## Summary

| | |
|---|---|
| EudraCT number | 2017-000505-20 |
| Trial protocol | DK |
| Global end of trial date | 03 December 2018 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 29 February 2020 |
| First version publication date | 29 February 2020 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | DEXNEF01 |

**Additional study identifiers**

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

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Eske K Aasvang |
| Sponsor organisation address | blegdamsvej 9, copenhagen, Denmark, |
| Public contact | Kristin Julia Steinthorsdottir, Rigshospitalet, 0045 31666112, kristin.julia.steinthorsdottir.01@regionh.dk |
| Scientific contact | Kristin Julia Steinthorsdottir, Rigshospitalet, 0045 31666112, kristin.julia.steinthorsdottir.01@regionh.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 | 20 February 2019 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 03 December 2018 |
| Was the trial ended prematurely? | Yes |

Notes:

## General information about the trial

Main objective of the trial:

To investigate the effect of high versus low dose intravenous dexamethasone on complications in the immediate postoperative setting after nephrectomy, heminephrectomy. Main objective complications demanding treatment in the post anaesthesia care unit (PACU) (pain, nausea).

Protection of trial subjects:

Trial subjects followed standard procedures. There was no extra distress or discomfort related to the trial.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 24 April 2017 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Denmark: 41 |
| Worldwide total number of subjects | 41 |
| EEA total number of subjects | 41 |

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) | 19 |
| From 65 to 84 years | 21 |
| 85 years and over | 1 |

## Subject disposition

### Recruitment

Recruitment details:

at preoperative appointment

### Pre-assignment

Screening details:

lægelig vurdering

### Period 1

| | |
|---|---|
| Period 1 title | overall (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Investigator, Monitor, Data analyst, Carer, Subject, Assessor |

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | 8 mg dexamethasone |

Arm description: -

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | dexamethasone |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Concentrate and solvent for concentrate for solution for infusion |
| Routes of administration | Intravenous bolus use |

Dosage and administration details:

8 mg iv bolus

| | |
|---|---|
| **Arm title** | 24 mg dexamethasone |

Arm description: -

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | dexamethasone |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Concentrate and solvent for concentrate for solution for infusion |
| Routes of administration | Intravenous bolus use |

Dosage and administration details:

24 mg iv bolus

| **Number of subjects in period 1** | 8 mg dexamethasone | 24 mg dexamethasone |
|---|---|---|
| Started | 19 | 22 |
| Completed | 19 | 22 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | overall |

Reporting group description: -

| Reporting group values | overall | Total | |
|---|---|---|---|
| Number of subjects | 41 | 41 | |
| Age categorical<br>Units: Subjects | | | |
| In utero | 0 | 0 | |
| 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) | 18 | 18 | |
| From 65-84 years | 22 | 22 | |
| 85 years and over | 1 | 1 | |
| all | 0 | 0 | |
| Age continuous<br>Units: years | | | |
| median | 67 | | |
| inter-quartile range (Q1-Q3) | 58 to 74 | - | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 10 | 10 | |
| Male | 31 | 31 | |
| height<br>Units: cm | | | |
| arithmetic mean | 178 | | |
| standard deviation | ± 8 | - | |
| weight<br>Units: kg | | | |
| arithmetic mean | 89 | | |
| standard deviation | ± 18 | - | |

## End points

| End points reporting groups | |
|---|---|
| Reporting group title | 8 mg dexamethasone |
| Reporting group description: - | |
| Reporting group title | 24 mg dexamethasone |
| Reporting group description: - | |

| Primary: Primary endpoint | |
|---|---|
| End point title | Primary endpoint |
| End point description:<br>Any complications (YES/NO) in the post-anesthesia care unit | |
| End point type | Primary |
| End point timeframe:<br>hours | |

| End point values | 8 mg dexamethasone | 24 mg dexamethasone | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 22 | | |
| Units: patients | | | | |
| YES | 13 | 18 | | |
| NO | 6 | 2 | | |
| missing | 0 | 2 | | |

### Statistical analyses

| Statistical analysis title | chi-square test |
|---|---|
| Comparison groups | 8 mg dexamethasone v 24 mg dexamethasone |
| Number of subjects included in analysis | 41 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.127 |
| Method | Chi-squared corrected |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.241 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.042 |
| upper limit | 1.388 |

## Adverse events

| Adverse events information[1] | |
|---|---|
| Timeframe for reporting adverse events:<br>60 hours from administration of study drug | |
| Assessment type | Systematic |

| Dictionary used | |
|---|---|
| Dictionary name | non used (no AE) |
| Dictionary version | 0 |

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: There were no non-serious adverse events recorded withj a frequency>5%

## 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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The trial was ended prematurely due to recruitment problems. Therefore only primary endpoint is reported. There were no differences between groups.

Notes: