



Clinical trial results:

A pharmacological trial with Sativex® and gentamicin for optimized pharmacological treatment of older patients with a focus on appetite stimulation and renal risk drugs

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2021-002318-15 |
| Trial protocol | DK |
| Global end of trial date | 29 January 2025 |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v1 (current) |
| This version publication date | 04 April 2026 |
| First version publication date | 04 April 2026 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 010921 |
|-----------------------|--------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Copenhagen University Hospital, Amager and Hvidovre |
| Sponsor organisation address | Kettegård Allé 30, Hvidovre, Denmark, 2650 |
| Public contact | Clinical Trial Information, Copenhagen University Hospital, Amager and Hvidovre, Department of Clinical Research , rikke.lundsgaard.nielsen@regionh.dk |
| Scientific contact | Clinical Trial Information, Copenhagen University Hospital, Amager and Hvidovre, Department of Clinical Research , 0045 40461306, rikke.lundsgaard.nielsen@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 | 01 October 2025 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 12 December 2024 |
| Global end of trial reached? | Yes |
| Global end of trial date | 29 January 2025 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

- Study 1:

To investigate if Sativex® has appetite stimulating properties defined as increased energy intake compared to placebo

Protection of trial subjects:

Protocol designed to minimize burden for patients such as duration, supply of food, transportation, ethical approvals, doctor on call, follow up by phone etc

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------------|
| Actual start date of recruitment | 01 September 2021 |
| 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: 73 |
| Worldwide total number of subjects | 73 |
| EEA total number of subjects | 73 |

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) | 0 |
| From 65 to 84 years | 63 |
| 85 years and over | 10 |

Subject disposition

Recruitment

Recruitment details:

Patients were included at the Emergency Department (ED) at Copenhagen University Hospital, Amager and Hvidovre, Denmark,

Pre-assignment

Screening details:

screening for poor appetite with snaq performed before inclusion, to ensure poor appetite

Period 1

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

Arms

| | |
|------------------------------|---------|
| Are arms mutually exclusive? | No |
| Arm title | Placebo |

Arm description: -

| | |
|--|------------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oromucosal spray, suspension |
| Routes of administration | Buccal use |

Dosage and administration details:

three sprays at two time points

| | |
|------------------|---------|
| Arm title | Sativex |
|------------------|---------|

Arm description: -

| | |
|--|------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Sativex |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oromucosal spray |
| Routes of administration | Buccal use |

Dosage and administration details:

3 sprays at two time points

| Number of subjects in period 1 | Placebo | Sativex |
|--------------------------------|---------|---------|
| Started | 17 | 17 |
| Wash out | 17 | 17 |
| Completed | 17 | 17 |

Baseline characteristics

Reporting groups^[1]

| | |
|--------------------------------|---------------|
| Reporting group title | Overall trial |
| Reporting group description: - | |

Notes:

[1] - The number of subjects reported to be in the baseline period is not equal to the worldwide number of subjects enrolled in the trial. It is expected that these numbers will be the same.

Justification: originally designed with three groups. two groupw where removed, a new sample size calculation were performed, showing 17 patients were needed

| Reporting group values | Overall trial | Total | |
|--|---------------|-------|--|
| Number of subjects | 17 | 17 | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | | 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) | | 0 | |
| From 65-84 years | | 0 | |
| 85 years and over | | 0 | |
| Age continuous | | | |
| Units: years | | | |
| median | 78 | | |
| inter-quartile range (Q1-Q3) | 71.2 to 85.9 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 13 | 13 | |
| Male | 4 | 4 | |

End points

End points reporting groups

| | |
|--------------------------------|---------|
| Reporting group title | Placebo |
| Reporting group description: - | |
| Reporting group title | Sativex |
| Reporting group description: - | |

Primary: to determine whether a standardized oromucosal spray containing a defined combination of THC and CBD was superior to placebo in improving caloric intake in older patients with poor appetite

| | |
|-----------------|---|
| End point title | to determine whether a standardized oromucosal spray containing a defined combination of THC and CBD was superior to placebo in improving caloric intake in older patients with poor appetite |
|-----------------|---|

End point description:

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

before and after administration of sativex compared to placebo on two different trial days with a two week wash out period

| End point values | Placebo | Sativex | | |
|---------------------------------------|---------------------------|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 17 | 17 | | |
| Units: Kcal | | | | |
| median (inter-quartile range (Q1-Q3)) | 575.07 (507.07 to 677.35) | 577.96 (505.90 to 671.38) | | |

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | Primary endpoint analysis |
| Comparison groups | Sativex v Placebo |
| Number of subjects included in analysis | 34 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 5 |
| Method | t-test, 2-sided |
| Parameter estimate | Median difference (final values) |
| Confidence interval | |
| level | 95 % |
| sides | 1-sided |
| Variability estimate | Standard deviation |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

During trial days and on follow up phone calls

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

Dictionary used

| | |
|-----------------|------|
| Dictionary name | None |
|-----------------|------|

| | |
|--------------------|---|
| Dictionary version | 0 |
|--------------------|---|

Reporting groups

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description: -

| | |
|-----------------------|---------|
| Reporting group title | Sativex |
|-----------------------|---------|

Reporting group description: -

| Serious adverse events | Placebo | Sativex | |
|---|----------------|-----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 2 / 17 (11.76%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| COPD exacerbation | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 17 (5.88%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 17 (5.88%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | Placebo | Sativex | |
|---|-----------------|------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 5 / 17 (29.41%) | 15 / 17 (88.24%) | |

| | | | |
|---|-----------------------|------------------------|--|
| Nervous system disorders Tirednes, vertigo, nausea, euphoira subjects affected / exposed occurrences (all) | 5 / 17 (29.41%) 21 | 15 / 17 (88.24%) 31 | |
|---|-----------------------|------------------------|--|

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|--------------|--|
| 01 July 2022 | <p>The following two protocol amendments have been approved by the Ethics Committee of the Capital Region of Denmark and are registered at ClinicalTrials.gov.</p> <p>Amendment #1: Removal of the secondary endpoint, in substudy 1, concerning eating patterns to relieve participants of extensive data collection. Additionally, the measurement of intraocular pressure in substudy 1 on follow-up days 1, 2, and 7 was removed, and it was specified that the result of the randomization in substudy 1 is not revealed to the project staff. Further, with additional approval from the Danish Medicines Agency, the exclusion criteria were clarified. Handgrip strength and biomarkers of ageing were added to substudy 2. Lastly, the total amount of blood collected in substudy 1 was corrected.</p> <p>Amendment #2: Follow-up visits and phone calls were optimized. The number of PK blood samples was reduced from 12 to 10 and the time points were adjusted. Re-screening with SNAQ was implemented if there were >14days from discharge until TD1. The dietary diary before TD1 and TD2 was removed. The time-point for the dessert was expedited to fit with a shorter TD1 and TD2. Lastly, funding details and information about trial staff were updated.</p> <p>Amendment #3: Removal of two groups, and change of sample size calculation, n=17 instead of 69</p> |

Notes:

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.

Originally designed to include 3 dosings regimen, hence 69 participants, it was changed to one group, and then a new sample size calculation that estimated a sample size of 17 patients

Notes: