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, transportion, 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 perfomed, 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 exerbation			
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	The following two protocol amendments have been approved by the Ethics Committee of the Capital Region of Denmark and are registered at ClinicalTrials.gov. 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. 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. Amendment #3: Removal of two groups, and change of sample size calculation, n=17 instead of 69

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 calulation that estimated a sample size of 17 patients

Notes: