Clinical trial results:
Desmopressin melt therapy in nocturnal polyuria patients: pharmacodynamic study

Summary

EudraCT number	2011-004560-29
Trial protocol	BE
Global end of trial date	01 February 2013

Results information

Result version number	v1 (current)
This version publication date	29 July 2021
First version publication date	29 July 2021
Summary attachment (see zip file)	Statement of discontinuation (2011-004560-29.docx)

Trial information

Trial identification

Sponsor protocol code	AGO/2011/010

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Ghent University Hospital
Sponsor organisation address	Corneel Heymanslaan 10, Ghent, Belgium, 9000
Public contact	Hiruz CTU, Ghent University Hospital, +32 93320500, hiruz.ctu@uzgent.be
Scientific contact	Hiruz CTU, Ghent University Hospital, +32 93320500, hiruz.ctu@uzgent.be

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 February 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 February 2013
Global end of trial reached?	Yes
Global end of trial date	01 February 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the pharmacodynamic (PD) characteristics of desmopressin melt in nocturia patients

Protection of trial subjects:

Ethics review and approval, informed consent, supportive care and routine monitoring.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 March 2012
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	Belgium: 5
Worldwide total number of subjects	5
EEA total number of subjects	5

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)	5
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

5 patients were screened in the period from 19-03-2012 till 1-02-2013 5 patients were included. 5 patients were randomised. 1 patient was included and completed the trial. End of trial notification was dated 1-02-2013.

Pre-assignment

Screening details:

Inclusion criteria:
- Written informed consent prior to the performance of any study-related activity
- Patients 18 years and older with an average of ≥ 2 nocturnal voids per night
- Evidence for nocturnal polyuria (nocturnal urine volume >33% of total volume over 24h), determined on frequency/volume chart
- Diuresis < 2,5L

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	Baseline arm

Arm description:

Baseline data for the study, as the study only has 1 arm.

Arm type	Baseline arm

No investigational medicinal product assigned in this arm

Arm title	Treatment arm

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Minirin Melt 60 µg
Investigational medicinal product code	CAS 62357-86-2
Other name	
Pharmaceutical forms	Oral lyophilisate
Routes of administration	Sublingual use

Dosage and administration details:

the patient has to take Minirin Melt 60 µg in the evening before going to bed instead of Minirin Melt 120 µg.
To reduce the risks, the start dose for this study will be 60 µg Minirin Melt instead of 120 µg. If the effect with desmopressin melt 60 µg is insufficient, the dosis can be increased to 120 µg.

Number of subjects in period 1	Baseline arm	Treatment arm
Started	5	5
Completed	5	1
Not completed	0	4
unknown	-	2
Adverse event, non-fatal	-	1
Lack of efficacy	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Baseline arm
Reporting group description:	
Baseline data for the study, as the study only has 1 arm.	
Reporting group title	Treatment arm
Reporting group description: -	

Reporting group values	Baseline arm	Treatment arm	Total
Number of subjects	5	5	5
Age categorical			
The 5 patients who participated in the study were classified in the age range of 18-64. The data of the study are no longer available so the age category could not be determined with 100% certainty.			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	5	5
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical			
The 5 patients who participated in the study were classified as male. The data of the study are no longer available so the gender category could not be determined with 100% certainty.			
Units: Subjects			
Female	0	0	0
Male	5	5	5

End points

End points reporting groups

Reporting group title	Baseline arm

Reporting group description:

Baseline data for the study, as the study only has 1 arm.

Reporting group title	Treatment arm

Reporting group description: -

Primary: Urine production

End point title	Urine production[1]

End point description:

End point type	Primary

End point timeframe:

Everyday during the first fourteen days.

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis available.

End point values	Baseline arm	Treatment arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[2]	1		
Units: liters				
number (not applicable)		0		

Notes:

[2] - Baseline data for the study, as the study only has 1 arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Blood analysis for safety profile

End point title	Blood analysis for safety profile

End point description:

End point type	Secondary

End point timeframe:

On day 3, 7 and 30 after the start of the treatment with desmopressin melt

End point values	Baseline arm	Treatment arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[3]	1		
Units: plasma concentration				
number (not applicable)		0		

Notes:

[3] - Baseline data for the study, as the study only has 1 arm.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Overall study	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	14

Reporting groups	
Reporting group title	Baseline arm
Reporting group description:	
Baseline data for the study, as the study only has 1 arm.	
Reporting group title	Treatment arm
Reporting group description: -	

Serious adverse events	Baseline arm	Treatment arm	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Baseline arm	Treatment arm	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	
General disorders and administration site conditions			
headache and nausea			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 March 2012	Reasons for the substantial amendment: Changes in safety or integrity of trial subjects, changes in interpretation of scientific documents/value of the trial, changes in quality of IMP(s), changes in conduct or management of the trial DESCRIPTION OF EACH SUBSTANTIAL AMENDMENT: - the patient has to take Minirin Melt 60 µg in the evening before going to bed instead of Minirin Melt 120 µg. To reduce the risks, the start dose for this study will be 60 µg Minirin Melt instead of 120 µg. If the effect with desmopressin melt 60 µg is insufficient, the dosis can be increased to 120 µg. -Addition of 2 new inclusion criteria (1) evidence for nocturnal polyuria (nocturnal urine volume >33% of total volume over 24h), determined on frequency/volume chart (2) diuresis <2,5L -Addition of 1 exclusion criterium and change in 1 of the exclusion criteria previous wording: moderate to severe renal insufficiency (creatinin clearance < 50 60 ml/min) new wording: suspicion or evidence of liver failure and moderate to severe renal insufficiency (creatinin clearance < 60 ml/min)

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.

The trial was early terminated due to a low inclusion rate.

Notes: