Clinical trial results:
Pharmacological treatment of hypersexual disorder; an open pilot study to evaluate the feasibility and effectiveness of treatment with Naltrexone

Summary

EudraCT number	2018-001049-15
Trial protocol	SE
Global end of trial date	29 September 2019

Results information

Result version number	v1 (current)
This version publication date	12 June 2021
First version publication date	12 June 2021

Trial information

Trial identification

Sponsor protocol code	HD-TREX

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	ANOVA Karolinska University Hopsital
Sponsor organisation address	Norra Stationsgatan 69, Stockholm, Sweden,
Public contact	Josephine Savard, ANOVA (Andrologi, Sexualmedicin, Transmedicin), 46 851773200, josephine.savard@sll.se
Scientific contact	Josephine Savard, ANOVA (Andrologi, Sexualmedicin, Transmedicin), 46 851773200, josephine.savard@sll.se

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	14 April 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 September 2019
Global end of trial reached?	Yes
Global end of trial date	29 September 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of this pilot study is to assess feasibility, efficacy and tolerability of Naltrexone treatment in patients with hypersexual disorder. The following research questions will be asked:
1. Is treatment with Naltrexone feasible for patients with Hypersexual disorder treated at a sub specialized unit?
2. Does Naltrexone reduce symptoms in patients with Hypersexual disorder? And if so, what clinical characteristics predict response?
3. What is the tolerability of Naltrexone in patients with Hypersexual disorder?

Protection of trial subjects:

Blood chemistry and adverse event monitoring

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 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	Sweden: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	20
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients seeking treatment due to troubled sexual behavior

Pre-assignment

Screening details:

37 men were screened, 20 were recrutied, 17 did not beet inclusion criteria mainly due to not meeting diagnose criteria

Pre-assignment period milestones

Number of subjects started	20
Number of subjects completed	20

Period 1

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

Arms

Arm title	main arm

Arm description: -

Arm type	Experimental
Investigational medicinal product name	naltrexone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

25-50 mg daily use

Number of subjects in period 1	main arm
Started	20
Completed	20

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	20	20	
Age categorical 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)	20	20	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	0	0	
Male	20	20	

Subject analysis sets	
Subject analysis set title	full anaysis
Subject analysis set type	Full analysis

Subject analysis set description:
all subjects

Reporting group values	full anaysis		
Number of subjects	20		
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)	20		
From 65-84 years	0		
85 years and over	0		

Gender categorical Units: Subjects			
Female	0		
Male	20		

End points

End points reporting groups	
Reporting group title	main arm
Reporting group description: -	
Subject analysis set title	full anaysis
Subject analysis set type	Full analysis
Subject analysis set description: all subjects	

Primary: main end point	
End point title	main end point
End point description:	
End point type	Primary
End point timeframe: after 4 weeks of treatment	

End point values	main arm	full anaysis		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20		
Units: 0-24 units	1	1		

Statistical analyses

Statistical analysis title	paired sample t-test
Statistical analysis description: Longitudinal data of same group (n=20) at two time points	
Comparison groups	main arm v full anaysis
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	5.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.9
upper limit	8
Variability estimate	Standard deviation

Adverse events

Adverse events information

Timeframe for reporting adverse events:

After 3-5 days with medication, weekly in the web-based plattform and at a consultation after 4 weeks. After 8 weeks (follow-up) adverse events were assessed. Bloodsamples were collected at baseline and after 4 weeks.

Assessment type	Systematic

Dictionary used

Dictionary name	PI designed
Dictionary version	1

Reporting groups

Reporting group title	sponsor

Reporting group description: -

Serious adverse events	sponsor		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	sponsor		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 20 (95.00%)		
Nervous system disorders			
Fatigue			
subjects affected / exposed	11 / 20 (55.00%)		
occurrences (all)	11		
Vertigo			
subjects affected / exposed	6 / 20 (30.00%)		
occurrences (all)	6		
Apathy			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	3		
Headache			

subjects affected / exposed occurrences (all) Nightmare subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2 1 / 20 (5.00%) 1		
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all) Abdominal pain subjects affected / exposed occurrences (all) Weight decreased subjects affected / exposed occurrences (all) Flatulence subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Constipation subjects affected / exposed occurrences (all)	 6 / 20 (30.00%) 6 6 / 20 (30.00%) 6 1 / 20 (5.00%) 1 1 / 20 (5.00%) 1 1 / 20 (5.00%) 1 1 / 20 (5.00%) 1		
Reproductive system and breast disorders Sexual dysfunction subjects affected / exposed occurrences (all)	 2 / 20 (10.00%) 2		
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) Depressed mood subjects affected / exposed occurrences (all)	 2 / 20 (10.00%) 2 1 / 20 (5.00%) 1		
Musculoskeletal and connective tissue disorders			

Back pain subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Infections and infestations Rhinitis subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/32532705