Clinical trial results:
Safety of intravesical bladder instillations among patients with severe interstitial cystitis

Summary

EudraCT number	2015-004495-30
Trial protocol	FI
Global end of trial date	02 October 2019

Results information

Result version number	v1 (current)
This version publication date	20 November 2024
First version publication date	20 November 2024

Trial information

Trial identification

Sponsor protocol code	CYCLOIC-1

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Oulu University Hospital
Sponsor organisation address	Kajaanintie 50, Oulu, Finland,
Public contact	Urologian avohoitoyksikkö, Oulu University Hospital, markku.h.vaarala@ppshp.fi
Scientific contact	Urologian avohoitoyksikkö, Oulu University Hospital, markku.h.vaarala@ppshp.fi

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	02 October 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 October 2019
Global end of trial reached?	Yes
Global end of trial date	02 October 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Safety of intravesical cyclosporine among patients with severe interstitial cystitis/painful bladder syndrome.

Protection of trial subjects:

Regular follow up.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2016
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Finland: 4
Worldwide total number of subjects	4
EEA total number of subjects	4

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)	4
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study subjects were recruited from the patients of the sponsor.

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	4
Number of subjects completed	4

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	cyclosporine

Arm description:

Experimental arm

Arm type	Experimental
Investigational medicinal product name	cyclosporine
Investigational medicinal product code	L04AD01
Other name	
Pharmaceutical forms	Bladder irrigation
Routes of administration	Instillation

Dosage and administration details:

Intravesical dose of 100 mg on day 1 and day 3. 200 mg on day 8 and day 10. 400 mg on day 15 and 17. 800 mg on day 22 and 24. The dose was reduced when needed.

Number of subjects in period 1	cyclosporine
Started	4
Completed	4

Baseline characteristics

Reporting groups

Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	4	4	
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			
arithmetic mean	58		
full range (min-max)	52 to 64	-	
Gender categorical Units: Subjects			
Female	1	1	
Male	3	3	

Subject analysis sets

Subject analysis set title	Cyclosporine dose
Subject analysis set type	Full analysis

Subject analysis set description:
Greatest tolerated cyclosporine dose

Subject analysis set title	Cyclosporine concentration
Subject analysis set type	Safety analysis

Subject analysis set description:
Cyclosporine concentrations in blood

Reporting group values	Cyclosporine dose	Cyclosporine concentration	
Number of subjects	4	4	
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			

Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	58	58	
full range (min-max)	52 to 64	52 to 64	
Gender categorical Units: Subjects			
Female	1	1	
Male	3	3	

End points

End points reporting groups

Reporting group title	cyclosporine
Reporting group description: Experimental arm	
Subject analysis set title	Cyclosporine dose
Subject analysis set type	Full analysis
Subject analysis set description: Greatest tolerated cyclosporine dose	
Subject analysis set title	Cyclosporine concentration
Subject analysis set type	Safety analysis
Subject analysis set description: Cyclosporine concentrations in blood	

Primary: Greatest tolerated cyclosporine dose

End point title	Greatest tolerated cyclosporine dose[1]
End point description:	
End point type	Primary
End point timeframe: 0 to 30 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: Only four subjects enrolled, so no statistical analyses were performed.

End point values	Cyclosporine dose			
Subject group type	Subject analysis set			
Number of subjects analysed	4			
Units: milligram(s)/dose				
number (not applicable)	800			

Attachments (see zip file)	Doses/doaw.xlsx

Statistical analyses

No statistical analyses for this end point

Secondary: Cyclosporine concentrations in blood

End point title	Cyclosporine concentrations in blood
End point description:	
End point type	Secondary
End point timeframe: 0-30 days.	

End point values	Cyclosporine concentration			
Subject group type	Subject analysis set			
Number of subjects analysed	4			
Units: microgram(s)/litre				
number (not applicable)	29			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 0 days- 30 days.	
Adverse event reporting additional description: Collected at the study visits.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	NCI-CTCAE
Dictionary version	4.0

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Serious adverse events	overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (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	overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)		
Cardiac disorders			
Hypertension			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		

Renal and urinary disorders Bladder pain subjects affected / exposed occurrences (all)	 4 / 4 (100.00%) 4		
Infections and infestations Cough subjects affected / exposed occurrences (all) Upper aerodigestive tract infection subjects affected / exposed occurrences (all)	 1 / 4 (25.00%) 1 1 / 4 (25.00%) 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