Clinical trial results:
Effect of topical antibiotics on duration of acute infective conjunctivitis in children: a randomized clinical trial

Summary

EudraCT number	2013-005623-16
Trial protocol	FI
Global end of trial date	07 February 2020

Results information

Result version number	v2 (current)
This version publication date	14 December 2024
First version publication date	17 November 2021
Version creation reason	• New data added to full data set Posting final results of the trial
Summary attachment (see zip file)	EudraCT_2013-005623-16 (EudraCT_2013-005623-16.pdf)

Trial information

Trial identification

Sponsor protocol code	OY122013

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, 90220
Public contact	Minna Honkila, Minna Honkila, minna.honkila@gmail.com
Scientific contact	Minna Honkila, Minna Honkila, minna.honkila@gmail.com

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	07 February 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 February 2020
Global end of trial reached?	Yes
Global end of trial date	07 February 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the benefits of antibiotic therapy in the management of acute conjunctivitis in children

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 October 2014
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	Finland: 95
Worldwide total number of subjects	95
EEA total number of subjects	95

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)	28
Children (2-11 years)	67
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

From October 15, 2014, to February 7, 2020

Pre-assignment

Screening details:

209 children with acute conjunctivitis were evaluated for eligibility; 114 children were excluded: 25 did not meet the inclusion criteria and 89 declined to participate

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, Carer

Blinding implementation details:

The eye drops and instructions were distributed in opaque cardboard boxes; the moxifloxacin eye drops were packed in plastic bottles and the placebo eye drops in single-dose vials; the bottles and the vials were transparent and did not have any labels

Arms

Are arms mutually exclusive?	Yes
Arm title	Active comparator

Arm description:

Moxifloxacin eye drops (5 mg/mL)

Arm type	Active comparator
Investigational medicinal product name	Vigamox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops
Routes of administration	Conjunctival use

Dosage and administration details:

1 drop in each affected eye 3 times daily until conjunctival symptoms were absent for at least 24 hours; the maximum duration of treatment was 7 days

Arm title	Placebo

Arm description:

Carboxymethylcellulose sodium (1.0%)

Arm type	Placebo
Investigational medicinal product name	Celluvisc
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops
Routes of administration	Conjunctival use

Dosage and administration details:

1 drop in each affected eye 3 times daily until conjunctival symptoms were absent for at least 24 hours; the maximum duration of treatment was 7 days

Arm title	No intervention

Arm description:

Removal of discharge from the child’s eyes at least 3 times a day

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Active comparator	Placebo	No intervention
Started	32	31	32
Completed	30	27	31
Not completed	2	4	1
Lost to follow-up	2	3	-
Protocol deviation	-	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Active comparator
Reporting group description:	
Moxifloxacin eye drops (5 mg/mL)	
Reporting group title	Placebo
Reporting group description:	
Carboxymethylcellulose sodium (1.0%)	
Reporting group title	No intervention
Reporting group description:	
Removal of discharge from the child’s eyes at least 3 times a day	

Reporting group values	Active comparator	Placebo	No intervention
Number of subjects	32	31	32
Age categorical			
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)	14	4	10
Children (2-11 years)	18	27	22
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	2.8	3.0	3.2
standard deviation	± 1.6	± 1.3	± 1.8
Gender categorical			
Units: Subjects			
Female	17	15	18
Male	15	16	14

Reporting group values	Total		
Number of subjects	95		
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)	28		
Children (2-11 years)	67		
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			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	50		
Male	45		

End points

End points reporting groups

Reporting group title	Active comparator
Reporting group description: Moxifloxacin eye drops (5 mg/mL)	
Reporting group title	Placebo
Reporting group description: Carboxymethylcellulose sodium (1.0%)	
Reporting group title	No intervention
Reporting group description: Removal of discharge from the child’s eyes at least 3 times a day	

Primary: Time to clinical cure

End point title	Time to clinical cure
End point description:	
End point type	Primary
End point timeframe: 14 days	

End point values	Active comparator	Placebo	No intervention	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	30	27	31	
Units: Days	30	27	31	

Statistical analyses

Statistical analysis title	Statistical analysis
Comparison groups	Active comparator v Placebo v No intervention
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	ANOVA

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 14 days	
Assessment type	Systematic
Dictionary used	
Dictionary name	NA
Dictionary version	NA
Reporting groups	
Reporting group title	Active comparator
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	No intervention
Reporting group description: -	

Serious adverse events	Active comparator	Placebo	No intervention
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	0 / 31 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

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

Non-serious adverse events	Active comparator	Placebo	No intervention
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 30 (16.67%)	2 / 27 (7.41%)	1 / 31 (3.23%)
Eye disorders			
Relapse			
subjects affected / exposed	5 / 30 (16.67%)	2 / 27 (7.41%)	1 / 31 (3.23%)
occurrences (all)	5	2	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/36194412