Clinical trial results:
Bath Additives for the Treatment of cHildhood Eczema (BATHE)

Summary

EudraCT number	2013-004589-32
Trial protocol	GB
Global end of trial date	01 March 2018

Results information

Result version number	v1 (current)
This version publication date	14 October 2020
First version publication date	14 October 2020

Trial information

Trial identification

Sponsor protocol code	7724

Additional study identifiers

ISRCTN number	ISRCTN84102309
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University of Southampton
Sponsor organisation address	University Rd, Southampton, United Kingdom, SO17 1BJ
Public contact	Dr Miriam Santer, University of Southampton, +44 02380241019, m.santer@soton.ac.uk
Scientific contact	Dr Miriam Santer, University of Southampton, +44 02380241019, m.santer@soton.ac.uk

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 March 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 March 2018
Global end of trial reached?	Yes
Global end of trial date	01 March 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the clinical and cost-effectiveness of bath emollient treatment, in addition to standard clinical care, for childhood eczema in primary care.

Protection of trial subjects:

None

Background therapy:

Both groups continued with standard eczema management, including leave-on emollients, and caregivers were given standardised advice on how to wash participants.

Evidence for comparator: -

Actual start date of recruitment	01 November 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 483
Worldwide total number of subjects	483
EEA total number of subjects	483

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)	29
Children (2-11 years)	454
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:

Recruitment took place in ninety-six general practices in Wales, the West of England, and southern England, from November 2014 to May 2016. The original target of 423 participants was reached in March 2016 and permission was obtained to continue recruiting participants up to an increased target of 491 participants.

Pre-assignment

Screening details:

Invitations were sent to the parents/carers of 12,504 children and responses were received from 1451. There were 920 completed screening questionnaire and 662 children met eligibility criteria and were approached regarding participation.

Period 1

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

Blinding implementation details:

This was an open trial, as it is not possible to create a convincing placebo for bath additives, with a primary outcome measure that was participant reported, as our main concern was with the impact of symptoms.

Arms

Are arms mutually exclusive?	Yes
Arm title	Standard management with bath additive

Arm description:

In addition to the child's usual skincare regimen, parents/carers were asked to use one of the three most commonly used bath additives Balneum, Aveeno, or Oilatum at least once per week, in accordance with the manufacturer's instructions.

Arm type	Experimental
Investigational medicinal product name	Balneum
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Bath additive
Routes of administration	Other use

Dosage and administration details:

At least once per week, in accordance with the manufacturer's instructions.

Investigational medicinal product name	Aveeno
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Bath additive
Routes of administration	Other use

Dosage and administration details:

At least once per week, in accordance with the manufacturer's instructions.

Investigational medicinal product name	Oilatum
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Bath additive
Routes of administration	Other use

Dosage and administration details:

At least once per week, in accordance with the manufacturer's instructions.

Arm title	Standard management, no bath additive
Arm description:	
The standard management of eczema in children without using bath emollient	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Standard management with bath additive	Standard management, no bath additive
Started	265	218
Completed	264	218
Not completed	1	0
Consent withdrawn by subject	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Standard management with bath additive
Reporting group description:	
In addition to the child's usual skincare regimen, parents/carers were asked to use one of the three most commonly used bath additives Balneum, Aveeno, or Oilatum at least once per week, in accordance with the manufacturer's instructions.	
Reporting group title	Standard management, no bath additive
Reporting group description:	
The standard management of eczema in children without using bath emollient	

Reporting group values	Standard management with bath additive	Standard management, no bath additive	Total
Number of subjects	265	218	483
Age categorical			
Units: Subjects			
Children between 1 year and 12 years	265	218	483
Age continuous			
Units: years			
arithmetic mean	5.4	5.2	
standard deviation	± 2.9	± 2.9	-
Gender categorical			
Units: Subjects			
Female	138	100	238
Male	127	118	245
Patient Oriented Eczema Measure (POEM)			
Units: score			
arithmetic mean	9.5	10.1	
standard deviation	± 5.7	± 5.8	-

End points

End points reporting groups

Reporting group title	Standard management with bath additive
Reporting group description:	
In addition to the child's usual skincare regimen, parents/carers were asked to use one of the three most commonly used bath additives Balneum, Aveeno, or Oilatum at least once per week, in accordance with the manufacturer's instructions.	
Reporting group title	Standard management, no bath additive
Reporting group description:	
The standard management of eczema in children without using bath emollient	

Primary: Patient Oriented Eczema Measure (POEM) at 16 weeks

End point title	Patient Oriented Eczema Measure (POEM) at 16 weeks
End point description:	
End point type	Primary
End point timeframe:	
16 weeks	

End point values	Standard management with bath additive	Standard management, no bath additive		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	264[1]	218		
Units: score				
arithmetic mean (standard deviation)	7.1 (± 6.1)	8.2 (± 6.3)		

Notes:

[1] - 1 participant withdraw data

Statistical analyses

Statistical analysis title	Patient Oriented Eczema Measure (POEM) week 16
Statistical analysis description:	
Interaction between treatment and time 0 to 16 weeks	
Comparison groups	Standard management with bath additive v Standard management, no bath additive
Number of subjects included in analysis	482
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.204 [2]
Method	Mixed models analysis

Notes:

[2] - The primary analysis for the total POEM score was performed using a mixed multilevel model (MMLM)
framework, with observations over time from weeks 1 to 16 (level 1) nested within participants (level 2) nested within recruiting centres (level 3).

Secondary: Number of eczema exacerbations resulting in a primary health-care consultation

End point title	Number of eczema exacerbations resulting in a primary health-care consultation

End point description:

The number of eczema exacerbations resulting in a primary health-care consultation, assessed by a review of participants' primary care records. Notes reviews were carried out by members of the trial team.

End point type	Secondary

End point timeframe:

52 weeks

End point values	Standard management with bath additive	Standard management, no bath additive		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	265	218		
Units: number of exacerbations				
median (inter-quartile range (Q1-Q3))	1 (0 to 2)	1 (0 to 3)		

Statistical analyses

Statistical analysis title	Number of exacerbation

Statistical analysis description:

Adjusted

Comparison groups	Standard management, no bath additive v Standard management with bath additive
Number of subjects included in analysis	483
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk ratio (RR)
Point estimate	1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.6

Secondary: Health-related quality of life_Utility values (CHU-9D)

End point title	Health-related quality of life_Utility values (CHU-9D)

End point description:

Child Health Utility-9 Dimensions captures issues pertinent to childhood eczema, such as sleep disturbance and the child’s mood.

End point type	Secondary

End point timeframe:

52 weeks

End point values	Standard management with bath additive	Standard management, no bath additive		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	150		
Units: score				
arithmetic mean (standard deviation)	0.9 (± 0.1)	0.91 (± 0.1)		

Statistical analyses

Statistical analysis title	Utility values (CHU-9D)
Comparison groups	Standard management with bath additive v Standard management, no bath additive
Number of subjects included in analysis	327
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Mean difference (final values)
Point estimate	-0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.03
upper limit	0.01

Secondary: Health-related quality of life_QALYs

End point title	Health-related quality of life_QALYs

End point description:

Reporting quality-adjusted life-years were estimated using the paediatric QoL measure CHU-9D.

End point type	Secondary

End point timeframe:

52 weeks

End point values	Standard management with bath additive	Standard management, no bath additive		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	174	147		
Units: score				
median (standard deviation)	0.91 (± 0.1)	0.90 (± 0.1)		

Statistical analyses

Statistical analysis title	QALYs
Comparison groups	Standard management with bath additive v Standard management, no bath additive
Number of subjects included in analysis	321
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Mean difference (final values)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.01
upper limit	0.02

Adverse events

Adverse events information

Timeframe for reporting adverse events:

52 weeks

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10

Reporting groups

Reporting group title	Standard management with bath additive

Reporting group description:

In addition to the child's usual skincare regimen, parents/carers were asked to use one of the three most commonly used bath additives Balneum, Aveeno, or Oilatum at least once per week, in accordance with the manufacturer's instructions.

Reporting group title	Standard management, no bath additive

Reporting group description:

The standard management of eczema in children without using bath emollient

Serious adverse events	Standard management with bath additive	Standard management, no bath additive	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 265 (0.00%)	0 / 218 (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	Standard management with bath additive	Standard management, no bath additive	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	137 / 265 (51.70%)	159 / 218 (72.94%)	
Investigations			
Refuses a bath			
subjects affected / exposed	30 / 265 (11.32%)	31 / 218 (14.22%)	
occurrences (all)	30	31	
Injury, poisoning and procedural complications			
Slips			

subjects affected / exposed	56 / 265 (21.13%)	63 / 218 (28.90%)	
occurrences (all)	56	63	
Skin and subcutaneous tissue disorders			
Stinging			
subjects affected / exposed	7 / 265 (2.64%)	4 / 218 (1.83%)	
occurrences (all)	7	4	
Redness			
subjects affected / exposed	44 / 265 (16.60%)	61 / 218 (27.98%)	
occurrences (all)	44	61	

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/30362939

http://www.ncbi.nlm.nih.gov/pubmed/29724749