Clinical trial results:
A randomised controlled trial of a new daily skincare regimen for lowering the incidence of pinsite infections following circular frame surgery

Summary

EudraCT number	2014-002223-10
Trial protocol	GB
Global end of trial date	25 August 2019

Results information

Result version number	v1 (current)
This version publication date	28 May 2021
First version publication date	28 May 2021
Summary attachment (see zip file)	The PINS Trial. A prospective randomised clinical trial comparing a traditional versus an emollient skincare regimen for the care of pin-sites in patients with circular frames. (bjj%20draft%20submission.pdf)

Trial information

Trial identification

Sponsor protocol code	R1762

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Hull and East Yorkshire Hospitals NHS Trust
Sponsor organisation address	Anlaby Road, Hull, United Kingdom, HU3 2JZ
Public contact	Hemant Sharma, Hull & East Yorkshire NHS Trust, +44 01482875875, hemant.sharma@hey.nhs.uk
Scientific contact	Hemant Sharma, Hull & East Yorkshire NHS Trust, +44 01482875875, hemant.sharma@hey.nhs.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	25 August 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 August 2019
Global end of trial reached?	Yes
Global end of trial date	25 August 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Does the use of an emmolient help protect the skin against pinsite infections following circular frame surgery?

Protection of trial subjects:

Patients were excluded if they suffered dementia or cognitive impairment, had known sensitivities to the trial medication, were felt unable to follow pin-site care regimens for any reason or were involved in another clinical trial investigating a medicinal product within the previous four weeks.
Patients were specifically educated regarding pin-site care prior to discharge from hospital by a member of the nursing staff.
Patients in the Chlorhexidine group that had sensitivities to their treatment resulting in skin irritation, itching and blistering in one case had the treatments changed to pinsite care with cooled boiled water or Dermol which resolved the irritation.

Background therapy:

No other treatments were given in the trial that were not test or comparator products.

Evidence for comparator:

The rate of pin site infection when using chlorhexidine solution has been reported in a previous Cochrane systematic review.

Lethaby A, Temple J, SantyTomlinson J. Pin site care for preventing infections associated with external bone fixators and pins. Cochrane Database of Systematic Reviews 2013, Issue 12. Art. No.: CD004551. DOI: 10.1002/14651858.CD004551.pub3.

Actual start date of recruitment	23 September 2015
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: 116
Worldwide total number of subjects	116
EEA total number of subjects	116

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)	99
From 65 to 84 years	16
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Adults aged 16+ with fracture of the tibia who were chosen for circular frame surgery. The participants were in the study for the full duration they had the circular frame on their leg, this was be on average of 4-6 months. The recruitment period for the trial was 1 year. Recruitment took place over two hospitals in Hull and Leeds .

Pre-assignment

Screening details:

Participants who presented themselves with fractured tibia were screened to see if they met the eligibility for the trial.
Between September 2015 and June 2017, a total of 235 patients were screened for recruitment into the trial 118 were subsequently enrolled. Two patients were withdrawn early because their treatment plans were changed .

Pre-assignment period milestones

Number of subjects started	116
Number of subjects completed	116

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Dermol arm

Arm description:

Self administering weekly skin emollient (Dermol).

Arm type	Experimental
Investigational medicinal product name	Dermol 500 skin emollient
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous emulsion
Routes of administration	Cutaneous use

Dosage and administration details:

To be applied once weekly to pinsites.

Arm title	Chlorhexidine arm

Arm description:

Participants were randomised to receive Chlorhexidine skin disinfectant

Arm type	Active comparator
Investigational medicinal product name	Chlorhexidine Gluconate 0.5% w/v in 70% v/v DEB
Investigational medicinal product code	
Other name	Hydrex 0.5%
Pharmaceutical forms	Cutaneous liquid
Routes of administration	Cutaneous use

Dosage and administration details:

Weekly application to pinsites

Investigational medicinal product name	Dermol 500 skin emollient
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous emulsion
Routes of administration	Cutaneous use

Dosage and administration details:

To be applied once weekly to pinsites.

Number of subjects in period 1	Dermol arm	Chlorhexidine arm
Started	57	59
Completed	57	59

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	116	116	
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)	99	99	
From 65-84 years	16	16	
85 years and over	1	1	
Gender categorical Units: Subjects			
Female	43	43	
Male	73	73	

End points

End points reporting groups	
Reporting group title	Dermol arm
Reporting group description: Self administering weekly skin emollient (Dermol).	
Reporting group title	Chlorhexidine arm
Reporting group description: Participants were randomised to receive Chlorhexidine skin disinfectant	

Primary: Pin Site Infections	
End point title	Pin Site Infections
End point description: Number of patients experiencing a pin site infection during the trial	
End point type	Primary
End point timeframe: Frame Duration	

End point values	Dermol arm	Chlorhexidine arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57[1]	59[2]		
Units: patients	26	23		

Notes:

[1] - Number of patients

[2] - Number of patients

Attachments (see zip file)	Demographics of Patients in Each Group/PINS Table 3.pdf Baseline Characteristics/PINS Table 4.pdf

Statistical analyses

Statistical analysis title	Comparison of CHX and DML on pin site infection
Comparison groups	Dermol arm v Chlorhexidine arm
Number of subjects included in analysis	116
Analysis specification	Post-hoc
Analysis type	equivalence
P-value	= 0.71
Method	Fisher exact

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The AE reporting period for this trial begins as soon as patients have consented to the trial and ends 30 days after the patient's circular frame is removed.

Adverse event reporting additional description:

The health status of subjects will be checked at each study visit. The investigator will record all directly observed AEs and all AEs spontaneously reported by the trial subject

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	Dermol arm

Reporting group description:

Self administering weekly skin emollient (Dermol).

Reporting group title	Chlorhexidine arm

Reporting group description:

Participants were randomised to receive Chlorhexidine skin disinfectant

Serious adverse events	Dermol arm	Chlorhexidine arm	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 57 (0.00%)	0 / 59 (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: 5 %

Non-serious adverse events	Dermol arm	Chlorhexidine arm	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 57 (0.00%)	4 / 59 (6.78%)	
Skin and subcutaneous tissue disorders			
Blister	Additional description: Skin blistering, redness and sensitivity to Chlorhexidine		
subjects affected / exposed	0 / 57 (0.00%)	4 / 59 (6.78%)	
occurrences (all)	0	4	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 May 2015	1. Principal Investigator in Leeds General Infirmary: Mr Paul Harwood (Consultant trauma and Orthopaedic Surgeon) 2. Trial Coordinator for Leeds General Infirmary and Hull Royal Infirmary: Mr David Ferguson (Orthopaedic Registrar) 3. Adverse Events and Serious Adverse Events that will not require reporting: a. Acute admissions for all non musculoskeletal conditions (e.g. appendicitis, pneumonia, newly diagnosed neoplasia.) b. Acute admissions for musculoskeletal condition unrelated to trial pathology (eg. – another trauma resulting in fracture / soft tissue injury etc, elective procedures ; Nerve decompressions etc) c. Abnormal blood results when this is not due to infection d. Admission to hospital for pinsite infections for less than 5 days e. New medical conditions that are not related to pinsite infections. f. Pin site infection requiring oral anitbiotics. g. Planned admission / procedures for trial condition eg. Bone grafting, reloading / dynamization / alteration of frame. 4. Research nurses will be permitted to take patient consent to enter the trial, and their names will appear on the delegation log. 5. Pinsite Grading system changed from Checketts and Otterburn to Clint et al. System. This is validated for use in the clinic environment. The previous scoring system could only be used retrospectively.

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.

There are several limitations to our study. There may be a small difference between treatment groups that we were unable to detect due to our sample size calculations for identifying a larger difference. This would lead our study to be underpowered,

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/33517738