# 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<br>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<br>Units: Subjects | | | |
| Female | 43 | 43 | |
| Male | 73 | 73 | |

## End points

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

| Primary: Pin Site Infections | |
|---|---|
| End point title | Pin Site Infections |
| End point description:<br>Number of patients experiencing a pin site infection during the trial | |
| End point type | Primary |
| End point timeframe:<br>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<br>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)<br>2. Trial Coordinator for Leeds General Infirmary and Hull Royal Infirmary: Mr David Ferguson (Orthopaedic Registrar)<br>3. Adverse Events and Serious Adverse Events that will not require reporting:<br>a. Acute admissions for all non musculoskeletal conditions (e.g. appendicitis, pneumonia, newly diagnosed neoplasia.)<br>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)<br>c. Abnormal blood results when this is not due to infection<br>d. Admission to hospital for pinsite infections for less than 5 days<br>e. New medical conditions that are not related to pinsite infections.<br>f. Pin site infection requiring oral anitbiotics.<br>g. Planned admission / procedures for trial condition eg. Bone grafting, reloading / dynamization / alteration of frame.<br>4. Research nurses will be permitted to take patient consent to enter the trial, and their names will appear on the delegation log.<br>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