



Clinical trial results: A Single-Blind Randomised Controlled Pilot trial of Corticosteroid Injection for Shoulder Pain

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2012-000147-27 |
| Trial protocol | GB |
| Global end of trial date | 31 March 2013 |

Results information

| | |
|-----------------------------------|--|
| Result version number | v1 (current) |
| This version publication date | 14 May 2016 |
| First version publication date | 14 May 2016 |
| Summary attachment (see zip file) | Final analysis published article (RCT2 Holt T (Trials 2013).pdf) |

Trial information

Trial identification

| | |
|-----------------------|--------------|
| Sponsor protocol code | TH/RCT2/0001 |
|-----------------------|--------------|

Additional study identifiers

| | |
|------------------------------------|----------------|
| ISRCTN number | ISRCTN82357435 |
| ClinicalTrials.gov id (NCT number) | - |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | University of Oxford |
| Sponsor organisation address | Block 60, Churchill Hospital, Oxford, United Kingdom, OX3 7LJ |
| Public contact | Dr Tim Holt, Nuffield Department of Primary Care Health Sciences University of Oxford, tim.holt@phc.ox.ac.uk |
| Scientific contact | Dr Tim Holt, Nuffield Department of Primary Care Health Sciences University of Oxford, tim.holt@phc.ox.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 | 31 July 2013 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 27 February 2013 |
| Global end of trial reached? | Yes |
| Global end of trial date | 31 March 2013 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To measure feasibility issues including rates of recruitment and loss to follow up, including withdrawal from a randomised trial of a corticosteroid shoulder injection in patients with rotator cuff tendinopathy or adhesive capsulitis.

Protection of trial subjects:

Risk assessment took place on 22/6/2016 to identify potential risks associated with the trial and IMP. Prior to recruitment of participants, trial GPs underwent study specific training in the assessment of shoulder pain, including the distinction of rotator cuff tendinopathy from adhesive capsulitis and the distinction of these two conditions and other disorders not relevant to this study. They also received training on the injection technique into the subacromial space employed in this trial. Training was led by an academic orthopedic shoulder surgeon from the Nuffield Orthopaedic Centre at Oxford and is based on the British Elbow and Shoulder Society (BESS) Pathway Guideline for Sub-acromial Pain. The trial GPs also received study specific good clinical practice (GCP) training and training in the study procedures (for example, case report form (CRF) completion, safety reporting) from the Primary Care Clinical Trials Unit. The training took less than 1 day to complete.

Background therapy:

The vials were sourced and labeled by Almac Clinical Services Ltd (Almac House, 20 Seagoe Industrial Estate, Craigavon, BT63 5QD, UK) and stored according to the manufactures specifications in the general practice premises.

Evidence for comparator:

Lidocaine is a medicine which is used in neuropathic pain.

| | |
|---|-------------------|
| Actual start date of recruitment | 01 September 2012 |
| 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 | United Kingdom: 40 |
| Worldwide total number of subjects | 40 |
| EEA total number of subjects | 40 |

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) | 30 |
| From 65 to 84 years | 10 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Participants were recruited between 20/9/2012 and 27/2/2013 from 6 GP practices within the Oxfordshire (UK) region

Pre-assignment

Screening details:

Forty nine people were screened for eligibility. Nine were excluded due to not eligible (n=7) and declined to participate (n=2)

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall trial (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Single blind |
| Roles blinded | Subject |

Blinding implementation details:

The trial injection was administered by the GP without disclosing to the participant which treatment they were receiving.

Arms

| | |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes |
| Arm title | Group M |

Arm description:

methylprednisolone acetate 40 mg with lidocaine 1% in 1 ml

| | |
|--|----------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | methylprednisolone acetate |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Periarticular use |

Dosage and administration details:

Total dose = 40mg (1 single injection)

| | |
|------------------|---------|
| Arm title | Group L |
|------------------|---------|

Arm description:

lidocaine 1% in 1 ml alone

| | |
|--|-------------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | lidocaine hydrochloride |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Periarticular use |

Dosage and administration details:

Total dose = 20mg (1 single injection)

| Number of subjects in period 1 | Group M | Group L |
|---------------------------------------|---------|---------|
| Started | 19 | 21 |
| Completed | 19 | 21 |

Baseline characteristics

Reporting groups

| | |
|--|---------|
| Reporting group title | Group M |
| Reporting group description: methylprednisolone acetate 40 mg with lidocaine 1% in 1 ml | |
| Reporting group title | Group L |
| Reporting group description: lidocaine 1% in 1 ml alone | |

| Reporting group values | Group M | Group L | Total |
|---|---------|---------|-------|
| Number of subjects | 19 | 21 | 40 |
| 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 | 61.5 | 56 | |
| standard deviation | ± 5.8 | ± 11.3 | - |
| Gender categorical Units: Subjects | | | |
| Female | 11 | 15 | 26 |
| Male | 8 | 6 | 14 |
| Which shoulder is affected Units: Subjects | | | |
| Right | 13 | 12 | 25 |
| Left | 6 | 9 | 15 |

Subject analysis sets

| | |
|---|--------------------|
| Subject analysis set title | ITT |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: All patients randomised irrespective of whether the participants received any trial medication | |

| Reporting group values | ITT | | |
|------------------------|-----|--|--|
| Number of subjects | 40 | | |

| | | | |
|--|-------|--|--|
| 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 | 58.6 | | |
| standard deviation | ± 9.4 | | |
| Gender categorical Units: Subjects | | | |
| Female | 26 | | |
| Male | 14 | | |
| Which shoulder is affected Units: Subjects | | | |
| Right | 25 | | |
| Left | 15 | | |

End points

End points reporting groups

| | |
|--|--------------------|
| Reporting group title | Group M |
| Reporting group description: | |
| methylprednisolone acetate 40 mg with lidocaine 1% in 1 ml | |
| Reporting group title | Group L |
| Reporting group description: | |
| lidocaine 1% in 1 ml alone | |
| Subject analysis set title | ITT |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| All patients randomised irrespective of whether the participants received any trial medication | |

Primary: Attrition rate at 2 weeks

| | |
|---------------------------------------|---------------------------|
| End point title | Attrition rate at 2 weeks |
| End point description: | |
| Number of questionnaires not returned | |
| End point type | Primary |
| End point timeframe: | |
| 2 weeks | |

| End point values | Group M | Group L | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 21 | | |
| Units: subjects | | | | |
| Yes | 0 | 0 | | |
| No | 19 | 21 | | |

Statistical analyses

| | |
|---|-------------------------------------|
| Statistical analysis title | Attrition rate - no formal analysis |
| Comparison groups | Group M v Group L |
| Number of subjects included in analysis | 40 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[1] |
| P-value | > 999 ^[2] |
| Method | N/A |

Notes:

[1] - This is a pilot study and therefore no formal statistical analysis was performed as stated in the statistical analysis plan

[2] - This P-value is N/A because there was no formal statistical comparison for this outcome because it's a pilot study

Primary: Compliance

| | |
|-----------------|------------|
| End point title | Compliance |
|-----------------|------------|

| | |
|---|---------|
| End point description: | |
| Number adhered to the allocated treatment | |
| End point type | Primary |
| End point timeframe: | |
| 12 weeks | |

| End point values | Group M | Group L | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 21 | | |
| Units: subjects | | | | |
| Adhered | 18 | 18 | | |

Statistical analyses

| | |
|---|-------------------|
| Statistical analysis title | Compliance |
| Statistical analysis description: | |
| Compliance with the allocated treatment | |
| Comparison groups | Group M v Group L |
| Number of subjects included in analysis | 40 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.607 |
| Method | Fisher exact |

Primary: Attrition rate at 4 weeks

| | |
|---------------------------------------|---------------------------|
| End point title | Attrition rate at 4 weeks |
| End point description: | |
| Number of questionnaires not returned | |
| End point type | Primary |
| End point timeframe: | |
| 4 weeks | |

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 21 | | |
| Units: Number of participants | | | | |
| Yes | 0 | 1 | | |
| No | 19 | 20 | | |

Statistical analyses

| | |
|---|-------------------------------------|
| Statistical analysis title | Attrition rate - no formal analysis |
| Comparison groups | Group M v Group L |
| Number of subjects included in analysis | 40 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[3] |
| P-value | = 999 ^[4] |
| Method | N/A |

Notes:

[3] - This is a pilot study and therefore no formal statistical analysis was performed as stated in the statistical analysis plan

[4] - This P-value is N/A because there was no formal statistical comparison for this outcome because it's a pilot study

Primary: Attrition rate at 12 weeks

| | |
|--------------------------------------|----------------------------|
| End point title | Attrition rate at 12 weeks |
| End point description: | |
| Number of questionnaire not returned | |
| End point type | Primary |
| End point timeframe: | |
| 12 weeks | |

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 21 | | |
| Units: Number of participants | | | | |
| Yes | 0 | 2 | | |
| No | 19 | 19 | | |

Statistical analyses

| | |
|---|-------------------------------------|
| Statistical analysis title | Attrition rate - no formal analysis |
| Comparison groups | Group M v Group L |
| Number of subjects included in analysis | 40 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[5] |
| P-value | = 999 ^[6] |
| Method | N/A |

Notes:

[5] - This is a pilot study and therefore no formal statistical analysis was performed as stated in the statistical analysis plan

[6] - This P-value is N/A because there was no formal statistical comparison for this outcome because it's a pilot study

Secondary: Change in OSS at 4 weeks

| | |
|------------------------|--------------------------|
| End point title | Change in OSS at 4 weeks |
| End point description: | |
| Oxford shoulder score | |
| End point type | Secondary |
| End point timeframe: | |
| 4 weeks | |

| End point values | Group M | Group L | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 21 | | |
| Units: point | | | | |
| arithmetic mean (standard deviation) | 3.9 (± 8.5) | 6.3 (± 10.1) | | |

Statistical analyses

| | |
|---|---------------------------------|
| Statistical analysis title | Change at 4 weeks from baseline |
| Comparison groups | Group M v Group L |
| Number of subjects included in analysis | 40 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | Mean difference (net) |
| Point estimate | -2.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.1 |
| upper limit | 3.4 |

Secondary: Change in OSS at 12 weeks

| | |
|---|---------------------------|
| End point title | Change in OSS at 12 weeks |
| End point description: | |
| Change in Oxford Shoulder Score from baseline | |
| End point type | Secondary |
| End point timeframe: | |
| 12 weeks | |

| End point values | Group M | Group L | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 21 | | |
| Units: points | | | | |
| arithmetic mean (standard deviation) | 4.2 (± 9.1) | 8.2 (± 11.3) | | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Change in OSS at 12 weeks from baseline |
| Comparison groups | Group M v Group L |
| Number of subjects included in analysis | 40 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Parameter estimate | Mean difference (net) |
| Point estimate | -2.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -9 |
| upper limit | 3.2 |

Secondary: Patient's satisfaction - problem with shoulder now? at 2 weeks

| | |
|------------------------|--|
| End point title | Patient's satisfaction - problem with shoulder now? at 2 weeks |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 2 weeks | |

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 21 | | |
| Units: Number of participants | | | | |
| Much worse | 1 | 2 | | |
| Slightly worse | 3 | 7 | | |
| No change | 3 | 5 | | |
| Slightly better | 10 | 4 | | |
| Much better | 1 | 2 | | |
| No problem at all | 1 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's satisfaction - problem with shoulder now? at 4 weeks

| | |
|-----------------|--|
| End point title | Patient's satisfaction - problem with shoulder now? at 4 weeks |
|-----------------|--|

End point description:

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

4 weeks

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 20 | | |
| Units: Number of participants | | | | |
| Much worse | 2 | 1 | | |
| Slightly worse | 1 | 2 | | |
| No change | 6 | 7 | | |
| Slightly better | 4 | 5 | | |
| Much better | 5 | 3 | | |
| No problem at all | 1 | 2 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's satisfaction - problem with shoulder now? at 12 weeks

| | |
|-----------------|---|
| End point title | Patient's satisfaction - problem with shoulder now? at 12 weeks |
|-----------------|---|

End point description:

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

12 weeks

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 19 | | |
| Units: Number of participants | | | | |
| Much worse | 0 | 0 | | |
| Slightly worse | 2 | 4 | | |
| No change | 8 | 3 | | |
| Slightly better | 3 | 3 | | |
| Much better | 5 | 8 | | |
| No problem at all | 1 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's satisfaction with injection - how pleased? 2 weeks

| | |
|-----------------|--|
| End point title | Patient's satisfaction with injection - how pleased? 2 weeks |
|-----------------|--|

End point description:

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

2 weeks

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 21 | | |
| Units: Number of participants | | | | |
| Very disappointed | 4 | 7 | | |
| Not very pleased | 5 | 9 | | |
| Fairly pleased | 9 | 3 | | |
| Very pleased | 1 | 2 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's satisfaction with injection - how pleased? 4 weeks

| | |
|-----------------|--|
| End point title | Patient's satisfaction with injection - how pleased? 4 weeks |
|-----------------|--|

End point description:

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

4 weeks

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 17 | 20 | | |
| Units: Number of participants | | | | |
| Very disappointed | 6 | 7 | | |
| Not very pleased | 3 | 6 | | |
| Fairly pleased | 4 | 4 | | |
| Very pleased | 4 | 3 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's satisfaction with injection - how pleased? 12 weeks

| | |
|------------------------|---|
| End point title | Patient's satisfaction with injection - how pleased? 12 weeks |
| End point description: | |

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

12 weeks

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 19 | | |
| Units: Number of participants | | | | |
| Very disappointed | 8 | 5 | | |
| Not very pleased | 2 | 5 | | |
| Fairly pleased | 5 | 5 | | |
| Very pleased | 4 | 4 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's satisfaction - still choose the injection? 2 weeks

| | |
|------------------------|--|
| End point title | Patient's satisfaction - still choose the injection? 2 weeks |
| End point description: | |

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

2 weeks

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 21 | | |
| Units: Number of participants | | | | |
| No | 3 | 7 | | |
| Yes | 14 | 10 | | |
| Not sure | 2 | 4 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's satisfaction - still choose the injection? 4 weeks

End point title Patient's satisfaction - still choose the injection? 4 weeks

End point description:

End point type Secondary

End point timeframe:

4 weeks

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 20 | | |
| Units: Number of participants | | | | |
| No | 1 | 4 | | |
| Yes | 14 | 11 | | |
| Not sure | 4 | 5 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's satisfaction - still choose the injection? 12 weeks

End point title Patient's satisfaction - still choose the injection? 12 weeks

End point description:

End point type Secondary

End point timeframe:

12 weeks

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 19 | | |
| Units: Number of participants | | | | |
| No | 4 | 4 | | |
| Yes | 12 | 10 | | |
| Not sure | 3 | 5 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Received other treatment - Pain killers: 2 weeks

End point title Received other treatment - Pain killers: 2 weeks

End point description:

End point type Other pre-specified

End point timeframe:

2 weeks

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 | 21 | | |
| Units: Number of participants | | | | |
| Yes | 8 | 11 | | |
| No | 10 | 4 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Received other treatment - Pain killers: 4 weeks

End point title Received other treatment - Pain killers: 4 weeks

End point description:

End point type Other pre-specified

End point timeframe:

4 weeks

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 20 | | |
| Units: Number of participants | | | | |
| Yes | 7 | 11 | | |
| No | 12 | 9 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Received other treatment - Pain killers: 12 weeks

End point title Received other treatment - Pain killers: 12 weeks

End point description:

End point type Other pre-specified

End point timeframe:

12 weeks

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 17 | 19 | | |
| Units: Number of participants | | | | |
| Yes | 7 | 11 | | |
| No | 10 | 8 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Received other treatment - anti-inflammatory medication: 2 weeks

End point title Received other treatment - anti-inflammatory medication: 2 weeks

End point description:

End point type Other pre-specified

End point timeframe:

4 weeks

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 | 20 | | |
| Units: Number of participants | | | | |
| Yes | 5 | 10 | | |
| No | 13 | 10 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Received other treatment - anti-inflammatory medication: 4 weeks

| | |
|-----------------|--|
| End point title | Received other treatment - anti-inflammatory medication: 4 weeks |
|-----------------|--|

End point description:

| | |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

4 weeks

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 17 | 19 | | |
| Units: Number of participants | | | | |
| Yes | 4 | 7 | | |
| No | 13 | 12 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Received other treatment - anti-inflammatory medication: 12 weeks

| | |
|-----------------|---|
| End point title | Received other treatment - anti-inflammatory medication: 12 weeks |
|-----------------|---|

End point description:

| | |
|----------------------|---------------------|
| End point type | Other pre-specified |
| End point timeframe: | |
| 12 weeks | |

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 16 | | |
| Units: Number of participants | | | | |
| Yes | 6 | 10 | | |
| No | 13 | 6 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Received other treatment - physiotherapy: 2 weeks

| | |
|------------------------|---|
| End point title | Received other treatment - physiotherapy: 2 weeks |
| End point description: | |

| | |
|----------------------|---------------------|
| End point type | Other pre-specified |
| End point timeframe: | |
| 2 weeks | |

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 17 | 20 | | |
| Units: Number of participants | | | | |
| Yes | 0 | 1 | | |
| No | 17 | 19 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Received other treatment - physiotherapy: 4 weeks

| | |
|------------------------|---|
| End point title | Received other treatment - physiotherapy: 4 weeks |
| End point description: | |

| | |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

4 weeks

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 16 | 19 | | |
| Units: Number of participants | | | | |
| Yes | 1 | 3 | | |
| No | 15 | 16 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Received other treatment - physiotherapy: 12 weeks

End point title Received other treatment - physiotherapy: 12 weeks

End point description:

End point type Other pre-specified

End point timeframe:

12 weeks

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 | 18 | | |
| Units: Number of participants | | | | |
| Yes | 1 | 6 | | |
| No | 17 | 12 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Received rescue steroid injection

End point title Received rescue steroid injection

End point description:

End point type Other pre-specified

End point timeframe:

12 weeks

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 21 | | |
| Units: Number of participants | | | | |
| Yes | 1 | 3 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Received physiotherapy in 12 weeks

| | |
|------------------------|------------------------------------|
| End point title | Received physiotherapy in 12 weeks |
| End point description: | |
| End point type | Other pre-specified |
| End point timeframe: | |
| 12 weeks | |

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 21 | | |
| Units: Number of participants | | | | |
| Yes | 3 | 3 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Received prescribed analgesia in 12 weeks

| | |
|------------------------|---|
| End point title | Received prescribed analgesia in 12 weeks |
| End point description: | |
| End point type | Other pre-specified |
| End point timeframe: | |
| 12 weeks | |

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 21 | | |
| Units: Number of participants | | | | |
| Yes | 2 | 2 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Received NSAID in 12 weeks

| | |
|------------------------|----------------------------|
| End point title | Received NSAID in 12 weeks |
| End point description: | |
| End point type | Other pre-specified |
| End point timeframe: | |
| 12 weeks | |

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 21 | | |
| Units: Number of participants | | | | |
| Yes | 1 | 6 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Treatment allocation blinding assessment

| | |
|--------------------------|--|
| End point title | Treatment allocation blinding assessment |
| End point description: | |
| End point type | Other pre-specified |
| End point timeframe: | |
| At the time of injection | |

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 21 | | |
| Units: Number of participants | | | | |
| 100% | 13 | 15 | | |
| 89-99% | 6 | 6 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Serious adverse event

| | |
|------------------------|-----------------------|
| End point title | Serious adverse event |
| End point description: | |
| | |
| End point type | Other pre-specified |
| End point timeframe: | |
| Throughout the trial | |

| End point values | Group M | Group L | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 21 | | |
| Units: Number of participants | | | | |
| Yes | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Adverse events reporting occurs through the entire duration of the study

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 15.1 |
|--------------------|------|

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: Both methylprednisolone acetate and lidocaine hydrochloride are commonly used medications in a primary care setting, have well defined safety profiles and are being used for authorised indications. As a result of this no non-serious adverse events will be recorded in this study.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|--|
| 13 November 2012 | <p>Substantial amendment with regards to putting up posters in the waiting rooms of the GP surgeries that are participating in the trial. The posters will ask patients if they have shoulder pain and if they match certain requirements of the inclusion criteria. The patients will be asked to speak with the trial GP at the practice for further information.</p> <p>In addition, to have patient leaflets in the reception areas of the GP surgeries. The leaflets will detail information about the trial and will ask the patient to contact the trial GP at the practice for further information. It is anticipated that these documents will help aid the practices in recruiting participants.</p> |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported