



Clinical trial results:

Different dosis of corticosteroids in mandibular third molar surgery. A randomized, blinded clinical trial assessing pain, trismus, edema and quality of life outcome measurements.

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2017-000622-35 |
| Trial protocol | DK |
| Global end of trial date | 01 July 2019 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 30 July 2019 |
| First version publication date | 30 July 2019 |

Trial information

Trial identification

| | |
|-----------------------|-------|
| Sponsor protocol code | 56872 |
|-----------------------|-------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Aalborg University Hospital |
| Sponsor organisation address | Hobrovej 18-22, Aalborg, Denmark, 9000 |
| Public contact | Department of Oral and Maxillofacial Surgery, Aalborg University Hospital, 0045 97 66 00 00, marie.kjaergaard@rn.d |
| Scientific contact | Department of Oral and Maxillofacial Surgery, Aalborg University Hospital, 0045 97 66 00 00, marie.kjaergaard@rn.dk |

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 July 2019 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 28 June 2019 |
| Global end of trial reached? | Yes |
| Global end of trial date | 01 July 2019 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To investigate the effects of treatment with intramuscular methylprednisolone on the postoperative morbidity after removal of mandibular third molar.

Protection of trial subjects:

Clinical examination

Background therapy: -

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 22 January 2018 |
| 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 | Denmark: 52 |
| Worldwide total number of subjects | 52 |
| EEA total number of subjects | 52 |

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) | 52 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Patients were recruited to the study from January to May 2018.

Pre-assignment

Screening details:

Medical assessment

Pre-assignment period milestones

| | |
|------------------------------|-------------------|
| Number of subjects started | 52 |
| Number of subjects completed | 52 ^[1] |

Notes:

[1] - The number of subjects reported to be in the pre-assignment period is not consistent with the number starting period 1. It is expected that the number completing the pre-assignment period are also present in the arms in period 1.

Justification: The study is a split-mouth trial. Every patient gets two arms.

Period 1

| | |
|------------------------------|---------------------------------|
| Period 1 title | Intervention (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Assessor |

Arms

| | |
|------------------------------|---------|
| Are arms mutually exclusive? | No |
| Arm title | Placebo |

Arm description: -

| | |
|--|-----------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Natriumklorid isotonisk SAD |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

2mL isotonic NaCl solution

| | |
|------------------|--------------------------|
| Arm title | 20 mg methylprednisolone |
|------------------|--------------------------|

Arm description: -

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Solu-Medrol |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

20 mg methylprednisolone

| | |
|------------------|--------------------------|
| Arm title | 30 mg methylprednisolone |
|------------------|--------------------------|

Arm description: -

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|--------------------------|
| Investigational medicinal product name | Solu-Medrol |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: | |
| 30 mg methylprednisolone | |
| Arm title | 40 mg methylprednisolone |
| Arm description: - | |
| Arm type | Experimental |
| Investigational medicinal product name | Solu-Medrol |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: | |
| 40 mg methylprednisolone | |

| Number of subjects in period 1 | Placebo | 20 mg methylprednisolone | 30 mg methylprednisolone |
|---------------------------------------|---------|-----------------------------|-----------------------------|
| Started | 26 | 26 | 26 |
| Completed | 26 | 26 | 26 |

| Number of subjects in period 1 | 40 mg methylprednisolone |
|---------------------------------------|-----------------------------|
| Started | 26 |
| Completed | 26 |

Baseline characteristics

Reporting groups

| Reporting group title | Intervention |
|--------------------------------|--------------|
| Reporting group description: - | |

| Reporting group values | Intervention | Total | |
|--|--------------|-------|--|
| Number of subjects | 52 | 52 | |
| 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 | | | |
| median | 25.9 | | |
| standard deviation | ± 6 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 36 | 36 | |
| Male | 16 | 16 | |
| Eosinophils | | | |
| Units: Amount | | | |
| median | 0.1 | | |
| standard deviation | ± 0.1 | - | |
| Leucocytes | | | |
| Units: Amount | | | |
| median | 6.3 | | |
| standard deviation | ± 1.4 | - | |
| Neutrophils | | | |
| Units: Amount | | | |
| median | 3.2 | | |
| standard deviation | ± 1.1 | - | |
| C-reactive protein | | | |
| Units: Amount | | | |
| median | 1.3 | | |
| standard deviation | ± 0.1 | - | |
| Trismus | | | |
| Units: mm | | | |
| median | 51 | | |
| standard deviation | ± 5.9 | - | |

| | | | |
|--------------------|------|---|--|
| Pain | | | |
| Units: mm | | | |
| median | 0 | | |
| standard deviation | ± 14 | - | |

Subject analysis sets

| | |
|----------------------------|-----------------|
| Subject analysis set title | Corticosteroids |
| Subject analysis set type | Full analysis |

Subject analysis set description:

The data contain data from 53 people, however one person is excluded due to missing values on a number of variables (including the treatment group). Thus all analyses are based on 52 people.

| Reporting group values | Corticosteroids | | |
|--|-----------------|--|--|
| Number of subjects | 52 | | |
| 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 | | | |
| median | 25.9 | | |
| standard deviation | ± 6 | | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 36 | | |
| Male | 16 | | |
| Eosinophils | | | |
| Units: Amount | | | |
| median | 0.1 | | |
| standard deviation | ± 0.1 | | |
| Leucocytes | | | |
| Units: Amount | | | |
| median | 6.3 | | |
| standard deviation | ± 1.4 | | |
| Neutrophils | | | |
| Units: Amount | | | |
| median | 3.2 | | |
| standard deviation | ± 1.1 | | |
| C-reactive protein | | | |
| Units: Amount | | | |
| median | 1.3 | | |
| standard deviation | ± 0.1 | | |

| | | | |
|--------------------|-----------|--|--|
| Trismus | | | |
| Units: mm | | | |
| median | 51 | | |
| standard deviation | ± 5.9 | | |
| Pain | | | |
| Units: mm | | | |
| median | 0 | | |
| standard deviation | ± 14 | | |

End points

End points reporting groups

| | |
|--|--------------------------|
| Reporting group title | Placebo |
| Reporting group description: - | |
| Reporting group title | 20 mg methylprednisolone |
| Reporting group description: - | |
| Reporting group title | 30 mg methylprednisolone |
| Reporting group description: - | |
| Reporting group title | 40 mg methylprednisolone |
| Reporting group description: - | |
| Subject analysis set title | Corticosteroids |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| The data contain data from 53 people, however one person is excluded due to missing values on a number of variables (including the treatment group). Thus all analyses are based on 52 people. | |

Primary: VAS

| | |
|--------------------------|---------|
| End point title | VAS |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| One days postoperatively | |

| End point values | Placebo | 20 mg methylprednisolone | 30 mg methylprednisolone | 40 mg methylprednisolone |
|-----------------------------|------------------|--------------------------|--------------------------|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 26 | 26 | 26 |
| Units: mm | | | | |
| median (standard deviation) | 52 (\pm 28.4) | 43.8 (\pm 25.5) | 41 (\pm 20.5) | 45.5 (\pm 22.5) |

Statistical analyses

| | |
|---|------------------------------------|
| Statistical analysis title | VAS Placebo-20mg |
| Comparison groups | Placebo v 20 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.53 |

| | |
|----------------------|----------------------------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -16.15 |
| upper limit | 15.1 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 8 |

| | |
|---|------------------------------------|
| Statistical analysis title | VAS Placebo-30mg |
| Comparison groups | Placebo v 30 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -11.77 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -27.88 |
| upper limit | 4.34 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 8.2 |

| | |
|---|------------------------------------|
| Statistical analysis title | VAS Placebo-40mg |
| Comparison groups | Placebo v 40 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.88 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -15.94 |
| upper limit | 14.18 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 7.7 |

Secondary: Trismus

| | |
|-----------------|---------|
| End point title | Trismus |
|-----------------|---------|

End point description:

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

End point timeframe:

Three days postoperatively

| End point values | Placebo | 20 mg methylprednisolone | 30 mg methylprednisolone | 40 mg methylprednisolone |
|-----------------------------|-----------------|--------------------------|--------------------------|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 26 | 26 | 26 |
| Units: mm | | | | |
| median (standard deviation) | 31.6 (± 9.5) | 31 (± 11.2) | 34.4 (± 8) | 32.9 (± 9.5) |

Statistical analyses

| | |
|---|------------------------------------|
| Statistical analysis title | Trismus Placebo-20mg |
| Comparison groups | Placebo v 20 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 1.23 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.71 |
| upper limit | 6.16 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.5 |

| | |
|---|------------------------------------|
| Statistical analysis title | Trismus Placebo-30mg |
| Comparison groups | Placebo v 30 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 1.44 |

| | |
|----------------------|----------------------------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.99 |
| upper limit | 6.87 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.8 |

| | |
|---|------------------------------------|
| Statistical analysis title | Trismus Placebo-40mg |
| Comparison groups | Placebo v 40 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 2.74 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.53 |
| upper limit | 8.01 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.7 |

Secondary: Leucocytes

| | |
|----------------------------|------------|
| End point title | Leucocytes |
| End point description: | |
| | |
| End point type | Secondary |
| End point timeframe: | |
| Three days postoperatively | |

| End point values | Placebo | 20 mg methylprednisolone | 30 mg methylprednisolone | 40 mg methylprednisolone |
|-----------------------------|-----------------|--------------------------|--------------------------|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 26 | 26 | 26 |
| Units: Number | | | | |
| median (standard deviation) | 7.2 (± 1.6) | 8.2 (± 2.2) | 8.3 (± 2.7) | 7.8 (± 2) |

Statistical analyses

| | |
|---|------------------------------------|
| Statistical analysis title | Leucocytes Placebo-20mg |
| Comparison groups | Placebo v 20 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.39 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.62 |
| upper limit | 1.4 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.5 |

| | |
|---|------------------------------------|
| Statistical analysis title | Leucocytes Placebo-30mg |
| Comparison groups | Placebo v 30 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.19 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.42 |
| upper limit | 1.04 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.63 |

| | |
|---|------------------------------------|
| Statistical analysis title | Leucocytes Placebo-40mg |
| Comparison groups | Placebo v 40 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.09 |

| | |
|----------------------|----------------------------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.98 |
| upper limit | 1.16 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.55 |

Secondary: Eosinophils

| | |
|----------------------------|-------------|
| End point title | Eosinophils |
| End point description: | |
| | |
| End point type | Secondary |
| End point timeframe: | |
| Three days postoperatively | |

| End point values | Placebo | 20 mg methylprednisolone | 30 mg methylprednisolone | 40 mg methylprednisolone |
|-----------------------------|-----------------|--------------------------|--------------------------|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 26 | 26 | 26 |
| Units: Amount | | | | |
| median (standard deviation) | 0.1 (± 0.1) | 0.2 (± 0.1) | 0.1 (± 0.1) | 0.1 (± 0.1) |

Statistical analyses

| | |
|---|------------------------------------|
| Statistical analysis title | Eosinophils Placebo-20mg |
| Comparison groups | Placebo v 20 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.01 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.03 |
| upper limit | 0.05 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.02 |

| | |
|---|------------------------------------|
| Statistical analysis title | Eosinophils Placebo-30mg |
| Comparison groups | Placebo v 30 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.001 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.04 |
| upper limit | 0.04 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.02 |

| | |
|---|------------------------------------|
| Statistical analysis title | Eosinophils Placebo-40mg |
| Comparison groups | Placebo v 40 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.005 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.04 |
| upper limit | 0.03 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.02 |

Secondary: Neutrophils

| | |
|----------------------------|-------------|
| End point title | Neutrophils |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| Three days postoperatively | |

| End point values | Placebo | 20 mg methylprednisolone | 30 mg methylprednisolone | 40 mg methylprednisolone |
|-----------------------------|-----------------|--------------------------|--------------------------|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 26 | 26 | 26 |
| Units: Amount | | | | |
| median (standard deviation) | 4.5 (± 1.7) | 5.2 (± 2) | 5.1 (± 2.3) | 4.7 (± 1.9) |

Statistical analyses

| | |
|---|------------------------------------|
| Statistical analysis title | Neutrophils Placebo-20mg |
| Comparison groups | Placebo v 20 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.27 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.64 |
| upper limit | 1.2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.5 |

| | |
|---|------------------------------------|
| Statistical analysis title | Neutrophils Placebo-30mg |
| Comparison groups | Placebo v 30 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.45 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.61 |
| upper limit | 0.72 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.59 |

| | |
|---|------------------------------------|
| Statistical analysis title | Neutrophils Placebo-40mg |
| Comparison groups | Placebo v 40 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.28 |
| upper limit | 0.68 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.5 |

Secondary: C-reactive protein

| | |
|----------------------------|--------------------|
| End point title | C-reactive protein |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| Three days postoperatively | |

| End point values | Placebo | 20 mg methylprednisolone | 30 mg methylprednisolone | 40 mg methylprednisolone |
|-----------------------------|-----------------|--------------------------|--------------------------|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 26 | 26 | 26 |
| Units: Amount | | | | |
| median (standard deviation) | 20.6 (± 24.3) | 16.1 (± 25.5) | 11.4 (± 13.4) | 11.5 (± 22.8) |

Statistical analyses

| | |
|-----------------------------------|------------------------------------|
| Statistical analysis title | C-reactive protein Placebo-20mg |
| Comparison groups | Placebo v 20 mg methylprednisolone |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -4.78 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -17.65 |
| upper limit | 8.08 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 6.6 |

| | |
|---|------------------------------------|
| Statistical analysis title | C-reactive protein Placebo-30mg |
| Comparison groups | Placebo v 30 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -10.26 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -20.31 |
| upper limit | -0.2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 5.1 |

| | |
|---|------------------------------------|
| Statistical analysis title | C-reactive protein Placebo-40mg |
| Comparison groups | Placebo v 40 mg methylprednisolone |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | GEE analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -9.92 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -22.17 |
| upper limit | 2.32 |

| | |
|----------------------|----------------------------|
| Variability estimate | Standard error of the mean |
| Dispersion value | 6.2 |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The time point is January 2019.

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

Dictionary used

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

| | |
|--------------------|----|
| Dictionary version | 20 |
|--------------------|----|

Reporting groups

| | |
|-----------------------|----------------|
| Reporting group title | Adverse events |
|-----------------------|----------------|

Reporting group description: -

| Serious adverse events | Adverse events | | |
|---|----------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

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

| Non-serious adverse events | Adverse events | | |
|---|------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 22 / 52 (42.31%) | | |
| Infections and infestations | | | |
| Infections | | | |
| subjects affected / exposed | 22 / 52 (42.31%) | | |
| occurrences (all) | 22 | | |

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