



Clinical trial results:

A Randomized, Single-blinded, Cross-over Study investigating the Non-inferiority of Efficacy and Safety of HyQvia in comparison with Conventional Subcutaneous Ig Therapy in Multifocal Motor Neuropathy

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2015-003453-18 |
| Trial protocol | DK |
| Global end of trial date | 03 May 2018 |

Results information

| | |
|-----------------------------------|---|
| Result version number | v1 (current) |
| This version publication date | 18 December 2020 |
| First version publication date | 18 December 2020 |
| Summary attachment (see zip file) | Abstract (HyQvia, Abstract, EudraCT.docx) |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | RH-2015-200 |
|-----------------------|-------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02556437 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Rigshospitalet - Department of Neurology |
| Sponsor organisation address | Blegdamsvej 9, Copenhagen, Denmark, |
| Public contact | Ali Al-Zuhairy, Rigshospitalet - Department of Neurology, 0045 22981147, al_zuhairy@hotmail.com |
| Scientific contact | Ali Al-Zuhairy, Rigshospitalet - Department of Neurology, 0045 22981147, al_zuhairy@hotmail.com |

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 | 03 May 2018 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 03 May 2018 |
| Global end of trial reached? | Yes |
| Global end of trial date | 03 May 2018 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of immunoglobulin administered together with hyaluronidase (HyQvia) in large doses subcutaneously compared to conventional treatment with subcutaneous immunoglobulin (Subcuvia) in patients with MMN

Protection of trial subjects:

This study was conducted in accordance with the recommendations of the International Conference on Harmonization (ICH) Guideline for Good Clinical Practice and was monitored by the the local GCP units throughout the study.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 01 December 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 | Denmark: 20 |
| Worldwide total number of subjects | 20 |
| EEA total number of subjects | 20 |

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) | 16 |
| From 65 to 84 years | 4 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Recruitment was conducted at all three departments in Denmark responsible for the treatment of multifocal motor neuropathy, the Department of Neurology, Aarhus University Hospital, the Department of Neurology, Odense University Hospital and Department of Neurology, Rigshospitalet, Copenhagen University Hospital.

Pre-assignment

Screening details:

Thirty-eight patients with MMN were screened. Eleven did not meet inclusion criteria and 7 declined to participate. Twenty were included.

Period 1

| | |
|------------------------------|---------------------------------------|
| Period 1 title | Baseline period |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Single blind ^[1] |
| Roles blinded | Data analyst, Assessor ^[2] |

Arms

| | |
|--|--|
| Arm title | Baseline |
| Arm description: - | |
| Arm type | Pre-study conventional SCIG |
| Investigational medicinal product name | Pre-study conventional subcutaneous immune globuline |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Patients receiving their regular conventional subcutaneous immune globuline at a stable dose for at least three months prior to inclusion.

Notes:

[1] - The number of roles blinded appears inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.

Justification: The same blinded person assessed the patients during study and upon study completion was unblinded and analyzed data.

[2] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: The same blinded person assessed the patients during study and upon study completion was unblinded and analyzed data.

| | |
|---------------------------------------|----------|
| Number of subjects in period 1 | Baseline |
| Started | 20 |
| Completed | 20 |

Period 2

| | |
|------------------------------|---------------------------------------|
| Period 2 title | First period of treatment |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Single blind ^[3] |
| Roles blinded | Data analyst, Assessor ^[4] |

Blinding implementation details:

All patients throughout the study were examined by the same assessor, who was blinded during the entire study.

Arms

| | |
|------------------------------|-----------------|
| Are arms mutually exclusive? | Yes |
| Arm title | fSCIG --> cSCIG |

Arm description:

Patients receiving facilitated subcutaneous immune globulin during the first 24 weeks of the study before crossing over

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | facilitated subcutaneous immune globuline |
| Investigational medicinal product code | |
| Other name | HyQvia |
| Pharmaceutical forms | Infusion |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Recombinant human hyaluronidase was manually injected at a dose of 80 U/g IgG followed by infusion of a 10% solution of human normal immunoglobulin (HyQvia, Shire, Lexington, MA, USA) [3] using an electronic peristaltic pump (Mini Rythmic PN+ R, Micrel Medical Devices, Athens, Greece). The maximum volume infused at one site was 600 ml at a rate of 300 ml/h.

| | |
|------------------|-----------------|
| Arm title | cSCIG --> fSCIG |
|------------------|-----------------|

Arm description:

Patients receiving conventional subcutaneous immune globulin for the first 24 weeks before crossing over

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | conventional subcutaneous immune globuline |
| Investigational medicinal product code | |
| Other name | Subcuvia |
| Pharmaceutical forms | Infusion |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Conventional SCIG was infused at a concentration of 16% human normal immunoglobulin (Subcuvia, Shire) [5] at the abdomen or the thighs using one or two mechanical pumps (Freedom Pump, RMS Medical Products, Chester, NY, USA), one or two 60 ml syringes and a maximum of four subcutaneous lines per pump. The average infusion speed was 20 ml/h with a maximum infusion volume of 20 ml at each site.

Notes:

[3] - The number of roles blinded appears inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.

Justification: The same blinded person assessed the patients during study and upon study completion was unblinded and analyzed data.

[4] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: The same blinded person assessed the patients during study and upon study completion was unblinded and analyzed data.

| Number of subjects in period 2 | fSCIG --> cSCIG | cSCIG --> fSCIG |
|--------------------------------|-----------------|-----------------|
| Started | 10 | 10 |
| Completed | 9 | 10 |
| Not completed | 1 | 0 |
| Adverse event, non-fatal | 1 | - |

Period 3

| | |
|------------------------------|--|
| Period 3 title | Second period of treatment, cross-over |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Single blind ^[5] |
| Roles blinded | Data analyst, Assessor ^[6] |

Arms

| | |
|------------------------------|-----------------|
| Are arms mutually exclusive? | Yes |
| Arm title | fSCIG --> cSCIG |

Arm description:

Patients treated with facilitated subcutaneous immune globulin for the first 24 weeks of study cross-over to 24 weeks of treatment with conventional subcutaneous immune globulin

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | conventional subcutaneous immune globuline |
| Investigational medicinal product code | |
| Other name | Subcuvia |
| Pharmaceutical forms | Infusion |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Please refer to previous description

| | |
|------------------|-----------------|
| Arm title | cSCIG --> fSCIG |
|------------------|-----------------|

Arm description:

Patients treated with conventional subcutaneous immune globulin for the first 24 weeks of study cross-over to 24 weeks of treatment with facilitated subcutaneous immune globulin

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | facilitated subcutaneous immune globuline |
| Investigational medicinal product code | |
| Other name | HyQvia |
| Pharmaceutical forms | Infusion |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Please refer to previous description

Notes:

[5] - The number of roles blinded appears inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.

Justification: The same blinded person assessed the patients during study and upon study completion was unblinded and analyzed data.

[6] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: The same blinded person assessed the patients during study and upon study completion was unblinded and analyzed data.

| Number of subjects in period 3 | fSCIG --> cSCIG | cSCIG --> fSCIG |
|---------------------------------------|-----------------|-----------------|
| Started | 9 | 10 |
| Completed | 9 | 10 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|-----------------|
| Reporting group title | Baseline period |
|-----------------------|-----------------|

Reporting group description: -

| Reporting group values | Baseline period | Total | |
|---|-----------------|-------|--|
| Number of subjects | 20 | 20 | |
| 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 | 54 | | |
| inter-quartile range (Q1-Q3) | 46.5 to 62.5 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 10 | 10 | |
| Male | 10 | 10 | |

End points

End points reporting groups

| | |
|---|-----------------------------|
| Reporting group title | Baseline |
| Reporting group description: - | |
| Reporting group title | fSCIG --> cSCIG |
| Reporting group description: Patients receiving facilitated subcutaneous immune globulin during the first 24 weeks of the study before crossing over | |
| Reporting group title | cSCIG --> fSCIG |
| Reporting group description: Patients receiving conventional subcutaneous immune globulin for the first 24 weeks before crossing over | |
| Reporting group title | fSCIG --> cSCIG |
| Reporting group description: Patients treated with facilitated subcutaneous immune globulin for the first 24 weeks of study cross-over to 24 weeks of treatment with conventional subcutaneous immune globulin | |
| Reporting group title | cSCIG --> fSCIG |
| Reporting group description: Patients treated with conventional subcutaneous immune globulin for the first 24 weeks of study cross-over to 24 weeks of treatment with facilitated subcutaneous immune globulin | |
| Subject analysis set title | fSCIG |
| Subject analysis set type | Modified intention-to-treat |
| Subject analysis set description: All patients following 24 weeks of treatment with facilitated subcutaneous immune globuline | |
| Subject analysis set title | cSCIG |
| Subject analysis set type | Modified intention-to-treat |
| Subject analysis set description: All patients following 24 weeks of treatment with conventional subcutaneous immune globuline | |

Primary: Normalized isometric strength

| | |
|------------------------|-------------------------------|
| End point title | Normalized isometric strength |
| End point description: | |
| | |
| End point type | Primary |
| End point timeframe: | |
| 24 weeks | |

| End point values | fSCIG | cSCIG | | |
|---|-----------------------|-----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 19 | 19 | | |
| Units: Percentage | | | | |
| arithmetic mean (confidence interval 95%) | 100.8 (94.5 to 107.1) | 105.9 (99.8 to 112.0) | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Non-inferiority test with a 15% margin |
| Comparison groups | fSCIG v cSCIG |
| Number of subjects included in analysis | 38 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[1] |
| P-value | = 0.0014 |
| Method | t-test, 1-sided |

Notes:

[1] - Since this is a paried design, the values of 19 patients following each therapy were compared.

Secondary: Medical Research Council (MRC)

| | |
|------------------------|--------------------------------|
| End point title | Medical Research Council (MRC) |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 24 weeks | |

| End point values | fSCIG | cSCIG | | |
|---------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 19 | 19 | | |
| Units: au | | | | |
| median (inter-quartile range (Q1-Q3)) | 88.0 (86.0 to 89.0) | 87.0 (84.0 to 89.0) | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Non-inferiority test with a 15% margin |
| Comparison groups | fSCIG v cSCIG |
| Number of subjects included in analysis | 38 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[2] |
| P-value | < 0.0001 |
| Method | t-test, 1-sided |

Notes:

[2] - Since this is a paried design, the values of 19 patients following each therapy were compared.

Secondary: Overall Disability Sum Score (ODSS)

| | |
|------------------------|-------------------------------------|
| End point title | Overall Disability Sum Score (ODSS) |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 24 weeks | |

| End point values | fSCIG | cSCIG | | |
|---------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 19 | 19 | | |
| Units: au | | | | |
| median (inter-quartile range (Q1-Q3)) | 2.0 (2.0 to 4.0) | 2.0 (2.0 to 4.0) | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Non-inferiority test with a 15% margin |
| Comparison groups | fSCIG v cSCIG |
| Number of subjects included in analysis | 38 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[3] |
| P-value | = 0.0007 |
| Method | t-test, 1-sided |

Notes:

[3] - Since this is a paried design, the values of 19 patients following each therapy were compared.

Secondary: 9-Hole Peg Test (9-HPT)

| | |
|------------------------|-------------------------|
| End point title | 9-Hole Peg Test (9-HPT) |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 24 weeks | |

| End point values | fSCIG | cSCIG | | |
|---------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 19 | 19 | | |
| Units: second | | | | |
| median (inter-quartile range (Q1-Q3)) | 25.4 (18.4 to 28.5) | 24.8 (18.1 to 28.4) | | |

Statistical analyses

| | |
|-----------------------------------|--|
| Statistical analysis title | Non-inferiority test with a 15% margin |
| Comparison groups | fSCIG v cSCIG |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 38 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[4] |
| P-value | = 0.0085 |
| Method | t-test, 1-sided |

Notes:

[4] - Since this is a paried design, the values of 19 patients following each therapy were compared.

Secondary: Grip strength

| | |
|------------------------|---------------|
| End point title | Grip strength |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 24 weeks | |

| End point values | fSCIG | cSCIG | | |
|---|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 19 | 19 | | |
| Units: kgf | | | | |
| arithmetic mean (confidence interval 95%) | 23.7 (17.1 to 30.3) | 22.6 (16.8 to 28.5) | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Non-inferiority test with a 15% margin |
| Comparison groups | fSCIG v cSCIG |
| Number of subjects included in analysis | 38 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[5] |
| P-value | < 0.0001 |
| Method | t-test, 1-sided |

Notes:

[5] - Since this is a paried design, the values of 19 patients following each therapy were compared.

Secondary: Sixt Spot Step Test

| | |
|------------------------|---------------------|
| End point title | Sixt Spot Step Test |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 24 weeks | |

| End point values | fSCIG | cSCIG | | |
|---|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 19 | 19 | | |
| Units: second | | | | |
| arithmetic mean (confidence interval 95%) | 6.5 (5.4 to 7.6) | 6.7 (5.6 to 7.7) | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Non-inferiority test with a 15% margin |
| Comparison groups | fSCIG v cSCIG |
| Number of subjects included in analysis | 38 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[6] |
| P-value | < 0.0001 |
| Method | t-test, 1-sided |

Notes:

[6] - Since this is a paried design, the values of 19 patients following each therapy were compared.

Secondary: EQ-5D-5L Index value

| | |
|------------------------|----------------------|
| End point title | EQ-5D-5L Index value |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 24 weeks | |

| End point values | fSCIG | cSCIG | | |
|---|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 19 | 19 | | |
| Units: au | | | | |
| arithmetic mean (confidence interval 95%) | 0.84 (0.78 to 0.91) | 0.81 (0.76 to 0.86) | | |

Statistical analyses

| | |
|-----------------------------------|--|
| Statistical analysis title | Non-inferiority test with a 15% margin |
| Comparison groups | fSCIG v cSCIG |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 38 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[7] |
| P-value | < 0.0001 |
| Method | t-test, 1-sided |

Notes:

[7] - Since this is a paired design, the values of 19 patients following each therapy were compared.

Secondary: EQ-5D-5L VAS

| | |
|------------------------|--------------|
| End point title | EQ-5D-5L VAS |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 24 weeks | |

| End point values | fSCIG | cSCIG | | |
|---------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 19 | 19 | | |
| Units: percent | | | | |
| median (inter-quartile range (Q1-Q3)) | 82.0 (65.0 to 95.0) | 85.0 (80.0 to 95.0) | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Non-inferiority test with a 15% margin |
| Comparison groups | fSCIG v cSCIG |
| Number of subjects included in analysis | 38 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[8] |
| P-value | = 0.0001 |
| Method | t-test, 1-sided |

Notes:

[8] - Since this is a paired design, the values of 19 patients following each therapy were compared.

Secondary: Headache or nausea

| | |
|---|--------------------|
| End point title | Headache or nausea |
| End point description: | |
| Number of patients experiencing headache or nausea at least once during the 24 weeks of therapy | |
| End point type | Secondary |
| End point timeframe: | |
| 24 weeks | |

| End point values | fSCIG | cSCIG | | |
|-----------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 16 | 16 | | |
| Units: At least once | 7 | 7 | | |

Statistical analyses

| Statistical analysis title | McNemar's test |
|--|----------------|
| Statistical analysis description: | |
| Only 16 subjects logged specifically every infusion and whether any systemic adverse event occurred or not. Since this is a paired design, only 16 subjects were compared. | |
| Comparison groups | fSCIG v cSCIG |
| Number of subjects included in analysis | 32 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.6 |
| Method | McNemar |

Secondary: Percentage of infusions causing local side-effects

| End point title | Percentage of infusions causing local side-effects |
|------------------------|--|
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 24 weeks | |

| End point values | fSCIG | cSCIG | | |
|---------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 14 | 14 | | |
| Units: percent | | | | |
| median (inter-quartile range (Q1-Q3)) | 62.6 (23.1 to 100.0) | 9.4 (0.0 to 21.7) | | |

Statistical analyses

| Statistical analysis title | Wilcoxon Signed Rank Test |
|----------------------------|---------------------------|
|----------------------------|---------------------------|

Statistical analysis description:

Only 14 patients had systematically logged all their infusions during both treatment periods with respect

to any side-effects. Since this is a paired design, the values of the 14 patients following each therapy were compared.

| | |
|---|---------------------------|
| Comparison groups | fSCIG v cSCIG |
| Number of subjects included in analysis | 28 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.005 |
| Method | Wilcoxon Signed Rank Test |

Secondary: Total infusions associated with local side-effects during the 24 weeks of each treatment

| | |
|------------------------|---|
| End point title | Total infusions associated with local side-effects during the 24 weeks of each treatment |
| End point description: | Total infusions associated with local side-effects during the 24 weeks period of each treatment |
| End point type | Secondary |
| End point timeframe: | 24 weeks |

| End point values | fSCIG | cSCIG | | |
|---------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 14 | 14 | | |
| Units: Infusions | | | | |
| median (inter-quartile range (Q1-Q3)) | 6.0 (3.0 to 13.0) | 2.5 (0.0 to 6.0) | | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Wilcoxon Signed Rank Test |
| Statistical analysis description: | Only 14 patients had systematically logged all their infusions during both treatment periods with respect to any side-effects. Since this is a paired design, the values of the 14 patients following each therapy were compared. |
| Comparison groups | fSCIG v cSCIG |
| Number of subjects included in analysis | 28 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 1 |
| Method | Wilcoxon Signed Rank Test |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

24 weeks

Adverse event reporting additional description:

Interviews every 6 weeks + patient logs

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

Dictionary used

| | |
|-----------------|-----------|
| Dictionary name | SNOMED CT |
|-----------------|-----------|

| | |
|--------------------|----------|
| Dictionary version | 20200930 |
|--------------------|----------|

Reporting groups

| | |
|-----------------------|-------|
| Reporting group title | fSCIG |
|-----------------------|-------|

Reporting group description: -

| | |
|-----------------------|-------|
| Reporting group title | cSCIG |
|-----------------------|-------|

Reporting group description: -

| Serious adverse events | fSCIG | cSCIG | |
|---|----------------|----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 20 (0.00%) | 0 / 19 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | | | |

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

| Non-serious adverse events | fSCIG | cSCIG | |
|---|------------------|------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 16 / 20 (80.00%) | 10 / 19 (52.63%) | |
| General disorders and administration site conditions | | | |
| Systemic and local side-effects | | | |
| subjects affected / exposed | 16 / 20 (80.00%) | 10 / 19 (52.63%) | |
| occurrences (all) | 16 | 10 | |

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