



Clinical trial results:

A Single Center, Randomized, Double-Blind, Placebo-Controlled Phase 2 Study of Gemcitabine (GEM) and Capecitabine (CAP) with or without T-ChOSTM as adjuvant therapy in patients with surgically resected pancreatic cancer

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2014-001163-12 |
| Trial protocol | DK |
| Global end of trial date | 10 July 2018 |

Results information

| | |
|--------------------------------|-------------------|
| Result version number | v1 (current) |
| This version publication date | 11 September 2020 |
| First version publication date | 11 September 2020 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | GI1604 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02767752 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Herlev University Hospital, Oncology Dept. |
| Sponsor organisation address | Herlev Ringvej 75, Herlev, Denmark, 2730 |
| Public contact | Herlev University Hospital, Oncolog Dept, Herlev University Hospital, Oncology Dept., 0045 38682344, dorte.nielsen.01@regionh.dk |
| Scientific contact | Herlev University Hospital, Oncology Dept, Herlev University Hospital, Oncology Dept., 0045 38682344, dorte.nielsen.01@regionh.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 | 31 July 2020 |
| Is this the analysis of the primary completion data? | No |

| | |
|----------------------------------|--------------|
| Global end of trial reached? | Yes |
| Global end of trial date | 10 July 2018 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

Disease-free survival (DFS), defined as the time from the date of randomization to the date of disease recurrence determined by investigator assessment of objective radiographic disease assessments per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1, or death, whichever is earlier.

Protection of trial subjects:

Patients with informed consent and fulfilling eligibility criteria were included. Continues monitoring of standard safety parameters during treatment.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 01 June 2016 |
| 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 | Denmark: 25 |
| Worldwide total number of subjects | 25 |
| EEA total number of subjects | 25 |

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) | 5 |
| From 65 to 84 years | 20 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

The trial was opened for recruitment in December 2016 and prematurely closed for recruitment in July 2018 as modified FOLFIRINOX replaced GEM/CAP as standard of care for fit patients such as the target population for this trial. Recruitment at single site, Herlev University Hospital, Denmark

Pre-assignment

Screening details:

Eligible patients were 18 years of age or older with histologically confirmed resected ductal pancreatic adenocarcinoma with macroscopic complete resection (R0 and R1). Time from resection to treatment start ≤ 12 weeks. Presence or history of metastatic or locally recurrent pancreatic adenocarcinoma was an exclusion criterion.

Pre-assignment period milestones

| | |
|--|---------------|
| Number of subjects started | 25 |
| Intermediate milestone: Number of subjects | Screening: 25 |
| Number of subjects completed | 21 |

Pre-assignment subject non-completion reasons

| | |
|----------------------------|--|
| Reason: Number of subjects | screen failure (recurrent/disseminated disease): 4 |
|----------------------------|--|

Period 1

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

Arms

| | |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes |
| Arm title | Placebo |

Arm description:

Backbone chemotherapy (gemcitabine / capecitabine) + Placebo

| | |
|--|----------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

600 mg daily for continuous oral intake until recurrence of disease

| | |
|--|---------------------------------------|
| Investigational medicinal product name | Gemcitabine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

1000 mg/m² on day 1, day 8 and day 15 of every 28-days cycle (total of 6 cycles)

| | |
|--|---------------------------------------|
| Investigational medicinal product name | Capecitabine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |
| Dosage and administration details: capecitabine 830 mg/m ² twice daily for 21 days out of the 28 days of a treatment cycle (total of 6 cycles) | |
| Arm title | T-ChOS |
| Arm description: Backbone chemotherapy (gemcitabine/capecitabine) + T-ChOs | |
| Arm type | Experimental |
| Investigational medicinal product name | T-ChOS |
| Investigational medicinal product code | |
| Other name | Benecta |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |
| Dosage and administration details: 600 mg daily for continuous oral intake until recurrence of disease | |
| Investigational medicinal product name | Gemcitabine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |
| Dosage and administration details: 1000 mg/m ² on day 1, day 8 and day 15 of every 28-days cycle (total of 6 cycles) | |
| Investigational medicinal product name | Capecitabine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |
| Dosage and administration details: capecitabine 830 mg/m ² twice daily for 21 days out of the 28 days of a treatment cycle (total of 6 cycles) | |

| Number of subjects in period 1^[1] | Placebo | T-ChOS |
|---|---------|--------|
| Started | 12 | 9 |
| Completed | 1 | 9 |
| Not completed | 11 | 0 |
| Unblinding at premature termination | 6 | - |
| Adverse event, non-fatal | 5 | - |

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: In total, 25 patients signed consent and were screened (pre-assignment period). Of those, 21 patients were eventually enrolled (treatment period) and 4 patients were screen failures (did not complete pre-assignment period)

Baseline characteristics

Reporting groups

| | |
|--|---------|
| Reporting group title | Placebo |
| Reporting group description: | |
| Backbone chemotherapy (gemcitabine / capecitabine) + Placebo | |
| Reporting group title | T-ChOS |
| Reporting group description: | |
| Backbone chemotherapy (gemcitabine/capecitabine) + T-ChOs | |

| Reporting group values | Placebo | T-ChOS | Total |
|--|----------|----------|-------|
| Number of subjects | 12 | 9 | 21 |
| 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 | 71 | 68 | |
| full range (min-max) | 59 to 80 | 61 to 72 | - |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 6 | 6 | 12 |
| Male | 6 | 3 | 9 |
| ECOG Performance status | | | |
| Units: Subjects | | | |
| ECOG 0 | 10 | 6 | 16 |
| ECOG 1 | 2 | 3 | 5 |
| Resection status | | | |
| Units: Subjects | | | |
| R0 | 9 | 7 | 16 |
| R1 | 3 | 2 | 5 |
| Nodal status | | | |
| Units: Subjects | | | |
| LN+ | 9 | 8 | 17 |
| LN- | 3 | 1 | 4 |

End points

End points reporting groups

| | |
|--|---------|
| Reporting group title | Placebo |
| Reporting group description: | |
| Backbone chemotherapy (gemcitabine / capecitabine) + Placebo | |
| Reporting group title | T-ChOS |
| Reporting group description: | |
| Backbone chemotherapy (gemcitabine/capecitabine) + T-ChOs | |

Primary: Disease Free Survival

| | |
|--|-----------------------|
| End point title | Disease Free Survival |
| End point description: | |
| | |
| End point type | Primary |
| End point timeframe: | |
| measured as the time from randomization to date of local tumor recurrence, lymph node spread, distant metastases, or death from any cause. | |

| End point values | Placebo | T-ChOS | | |
|----------------------------------|-----------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12 | 9 | | |
| Units: months | | | | |
| median (confidence interval 95%) | 8.4 (0 to 21.5) | 10.8 (5.9 to 15.7) | | |

Statistical analyses

| | |
|---|-------------------|
| Statistical analysis title | primary endpoint |
| Comparison groups | Placebo v T-ChOS |
| Number of subjects included in analysis | 21 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.57 |
| Method | Logrank |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.34 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.49 |
| upper limit | 3.69 |

Secondary: Overall Survival

| | |
|-----------------|------------------|
| End point title | Overall Survival |
|-----------------|------------------|

End point description:

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

End point timeframe:

Time from randomisation to death

| End point values | Placebo | T-ChOS | | |
|----------------------------------|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12 ^[1] | 9 | | |
| Units: months | | | | |
| median (confidence interval 95%) | 31.3 (0 to 99) | 33.9 (22.3 to 45.6) | | |

Notes:

[1] - The CI in this group is not calculatable at time of analyse

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

from signed Informed consent to 30 days after treatment stop

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

Dictionary used

| | |
|-----------------|-----------|
| Dictionary name | NCI-CTCAE |
|-----------------|-----------|

| | |
|--------------------|---|
| Dictionary version | 4 |
|--------------------|---|

Reporting groups

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Backbone chemotherapy (gemcitabine / capecitabine) + Placebo

| | |
|-----------------------|--------|
| Reporting group title | T-ChOS |
|-----------------------|--------|

Reporting group description:

Backbone chemotherapy (gemcitabine/capecitabine) + T-ChOs

| Serious adverse events | Placebo | T-ChOS | |
|---|-----------------|----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 9 / 12 (75.00%) | 3 / 9 (33.33%) | |
| number of deaths (all causes) | 6 | 5 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Vascular disorders | | | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 0 / 9 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombophlebitis | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 9 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Chest pain | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 9 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Cerebral infarction | | | |

| | | | |
|--|-----------------|----------------|--|
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 9 (11.11%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Fever | | | |
| subjects affected / exposed | 4 / 12 (33.33%) | 1 / 9 (11.11%) | |
| occurrences causally related to treatment / all | 3 / 4 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Edema limbs | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 9 (11.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 0 / 9 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 1 / 9 (11.11%) | |
| occurrences causally related to treatment / all | 1 / 2 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Constipation | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 9 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Volvulus | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 9 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Pneumonitis | | | |

| | | | |
|---|----------------|----------------|--|
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 9 (11.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Skin infection | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 9 (11.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sepsis | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 9 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary tract infection | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 9 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 9 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | Placebo | T-ChOS | |
|--|-------------------|-----------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 12 / 12 (100.00%) | 9 / 9 (100.00%) | |
| Vascular disorders | | | |
| Thrombophlebitis | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 9 (11.11%) | |
| occurrences (all) | 1 | 1 | |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 8 / 12 (66.67%) | 6 / 9 (66.67%) | |
| occurrences (all) | 9 | 11 | |

| | | | |
|---|-----------------|----------------|--|
| Flu-like symptoms | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 0 / 9 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| common cold | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 2 / 9 (22.22%) | |
| occurrences (all) | 0 | 2 | |
| Fever | | | |
| subjects affected / exposed | 3 / 12 (25.00%) | 2 / 9 (22.22%) | |
| occurrences (all) | 3 | 3 | |
| Pain | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 3 / 9 (33.33%) | |
| occurrences (all) | 4 | 4 | |
| Edema limbs | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 2 / 9 (22.22%) | |
| occurrences (all) | 2 | 2 | |
| Injection site reaction | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 0 / 9 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Weight loss | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 9 (11.11%) | |
| occurrences (all) | 0 | 1 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 9 (11.11%) | |
| occurrences (all) | 0 | 1 | |
| Investigations | | | |
| Neutropenia | | | |
| subjects affected / exposed | 8 / 12 (66.67%) | 7 / 9 (77.78%) | |
| occurrences (all) | 14 | 26 | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 4 / 9 (44.44%) | |
| occurrences (all) | 3 | 8 | |
| Cardiac disorders | | | |
| Chest pain | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 9 (0.00%) | |
| occurrences (all) | 1 | 0 | |

| | | | |
|--|-----------------|----------------|--|
| Nervous system disorders | | | |
| Cerebral infarction | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 9 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 9 (11.11%) | |
| occurrences (all) | 0 | 1 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 3 / 9 (33.33%) | |
| occurrences (all) | 3 | 4 | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 0 / 9 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 7 / 12 (58.33%) | 6 / 9 (66.67%) | |
| occurrences (all) | 7 | 10 | |
| Nausea | | | |
| subjects affected / exposed | 5 / 12 (41.67%) | 5 / 9 (55.56%) | |
| occurrences (all) | 8 | 8 | |
| Vomiting | | | |
| subjects affected / exposed | 3 / 12 (25.00%) | 2 / 9 (22.22%) | |
| occurrences (all) | 4 | 3 | |
| Anorexia | | | |
| subjects affected / exposed | 7 / 12 (58.33%) | 4 / 9 (44.44%) | |
| occurrences (all) | 11 | 8 | |
| Mucositis oral | | | |
| subjects affected / exposed | 7 / 12 (58.33%) | 5 / 9 (55.56%) | |
| occurrences (all) | 13 | 9 | |
| Hemorrhoids | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 9 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Meteorism | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 9 (11.11%) | |
| occurrences (all) | 0 | 1 | |
| Skin and subcutaneous tissue disorders | | | |

| | | | |
|---|-----------------|----------------|--|
| Palmar-plantar erythrodysesthesia syndrome | | | |
| subjects affected / exposed | 9 / 12 (75.00%) | 7 / 9 (77.78%) | |
| occurrences (all) | 22 | 18 | |
| Rash | | | |
| subjects affected / exposed | 4 / 12 (33.33%) | 1 / 9 (11.11%) | |
| occurrences (all) | 4 | 1 | |
| Pruritus | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 9 (11.11%) | |
| occurrences (all) | 0 | 1 | |
| Dry skin | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 9 (11.11%) | |
| occurrences (all) | 0 | 1 | |
| Alopecia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 9 (11.11%) | |
| occurrences (all) | 0 | 1 | |
| Wound | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 9 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Renal and urinary disorders | | | |
| Dysuria | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 9 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Myalgia | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 9 (11.11%) | |
| occurrences (all) | 1 | 1 | |
| Infections and infestations | | | |
| Infections | | | |
| subjects affected / exposed | 5 / 12 (41.67%) | 4 / 9 (44.44%) | |
| occurrences (all) | 8 | 6 | |
| Metabolism and nutrition disorders | | | |
| Hypokalaemia | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 9 (11.11%) | |
| occurrences (all) | 1 | 1 | |

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

| |
|--|
| premature termination of recruitment - due to change in SOC, only 21 out of 180 planned patients included at that time |
|--|

Notes: