



Clinical trial results:

Predictive value of in-vitro testing anti-cancer therapy sensitivity on tumoroids from patients with metastatic pancreatic cancer

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2018-003112-53 |
| Trial protocol | DK |
| Global end of trial date | 22 February 2023 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 18 January 2024 |
| First version publication date | 18 January 2024 |

Trial information

Trial identification

| | |
|-----------------------|-----|
| Sponsor protocol code | TIP |
|-----------------------|-----|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03821870 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Vejle Hospital |
| Sponsor organisation address | Beriderbakken 4, Vejle, Denmark, 7100 |
| Public contact | Clinical Trial Unit, Oncology, Vejle Hospital, karin.larsen1@rsyd.dk |
| Scientific contact | Clinical Trial Unit, Oncology, Vejle Hospital, karin.larsen1@rsyd.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 | 02 January 2024 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 22 February 2022 |
| Global end of trial reached? | Yes |
| Global end of trial date | 22 February 2023 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

The purpose of the present study is to investigate the predictive value of pretreatment in-vitro testing of drug sensitivity to patient-derived tumoroids.

Protection of trial subjects:

Antiemetics and other supportive treatment as necessary

Background therapy: -

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 01 October 2018 |
| 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: 12 |
| Worldwide total number of subjects | 12 |
| EEA total number of subjects | 12 |

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) | 2 |
| From 65 to 84 years | 10 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Patients were included between February and October 2019.

Pre-assignment

Screening details:

Institution-based screening of all patients with non-resectable pancreatic cancer.

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall trial (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|-----------|------------------|
| Arm title | Precision cohort |
|-----------|------------------|

Arm description:

Patients with one histopathologic tumor type, pancreatic adenocarcinoma, are subdivided into treatment groups based on functional characteristics.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Targeted treatment |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder and solvent for concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

FOLFIRINOX .

Gemcitabine + Albumin-bound Paclitaxel.

Gemcitabine + Erlotinib.

Gemcitabine + Capecitabine.

Gemcitabine + Cisplatin.

Gemcitabine + docetaxel + capecitabine.

CAPOX: Day 1: Oxaliplatin 130 mg/m² IV. Days 1–14: Capecitabine 1,000 m

FOLFIRI: Day 1: irinotecan 180 mg/m² IV + leucovorin 400 mg/m² IV + 5-FU 400 mg/m² IV bolus and 5-FU 2,400 mg/m² IV for 46 h. Repeat every 2 weeks.

Olaparib: 300 mg orally twice daily.

| | |
|---|------------------|
| Number of subjects in period 1^[1] | Precision cohort |
| Started | 9 |
| Completed | 9 |

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: 30 patients were planned. 12 were included. 9 started treatment of which none were evaluable for the primary endpoint.

Baseline characteristics

Reporting groups

Reporting group title

Overall trial

Reporting group description: -

| Reporting group values | Overall trial | Total | |
|---|---------------|-------|--|
| Number of subjects | 9 | 9 | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 2 | 2 | |
| From 65-84 years | 7 | 7 | |
| 85 years and over | 0 | 0 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 5 | 5 | |
| Male | 4 | 4 | |

End points

End points reporting groups

| | |
|--|------------------|
| Reporting group title | Precision cohort |
| Reporting group description: Patients with one histopathologic tumor type, pancreatic adenocarcinoma, are subdivided into treatment groups based on functional characteristics. | |

Primary: Response rate

| | |
|------------------------|------------------------------|
| End point title | Response rate ^[1] |
| End point description: | |

| | |
|----------------------------------|---------|
| End point type | Primary |
| End point timeframe: 6 months | |

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Not relevant since no patients were evaluable.

| | | | | |
|-----------------------------|------------------|--|--|--|
| End point values | Precision cohort | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 0 ^[2] | | | |
| Units: Number | | | | |

Notes:

[2] - No patients were evaluable.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Every 3-4 weeks.

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

Dictionary used

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

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

Reporting groups

| | |
|-----------------------|---------------|
| Reporting group title | Overall group |
|-----------------------|---------------|

Reporting group description: -

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: Only data on grade 3-5 events were collected.

| Serious adverse events | Overall group | | |
|---|----------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 6 / 9 (66.67%) | | |
| number of deaths (all causes) | 8 | | |
| number of deaths resulting from adverse events | 1 | | |
| Cardiac disorders | | | |
| Heart failure | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Ventricular arrhythmia | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Pneumonitis | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Infection | | | |
| subjects affected / exposed | 2 / 9 (22.22%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| | | | |
|---|---------------|--|--|
| Non-serious adverse events | Overall group | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |

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