



Clinical trial results: Photodynamic therapy without curettage Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2017-001701-33 |
| Trial protocol | DK |
| Global end of trial date | 14 December 2017 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 02 July 2020 |
| First version publication date | 02 July 2020 |

Trial information

Trial identification

| | |
|-----------------------|-------|
| Sponsor protocol code | 58161 |
|-----------------------|-------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Bispebjerg Hospital |
| Sponsor organisation address | Bispebjerg Bakke 23, Copenhagen NV, Denmark, |
| Public contact | Department of Dermatology, D92, Bispebjerg Hospital, hans.christian.wulf@regionh.dk |
| Scientific contact | Department of Dermatology, D92, Bispebjerg Hospital, hans.christian.wulf@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 | 03 December 2018 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 14 December 2017 |
| Global end of trial reached? | Yes |
| Global end of trial date | 14 December 2017 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

Investigate if photodynamic therapy without curettage is equally effective as photodynamic therapy with curettage.

Protection of trial subjects:

No special protection was needed.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 15 June 2017 |
| 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: 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) | 2 |
| From 65 to 84 years | 20 |
| 85 years and over | 3 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients were recruited from Department of Dermatology, Bispebjerg Hospital.

Period 1

| | |
|------------------------------|----------------------------------|
| Period 1 title | Baseline period (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Single blind |
| Roles blinded | Investigator ^[1] |

Blinding implementation details:

The subjects were not blinded. The treatments were performed by a non blinded investigator. The treatment efficacy evaluations were performed by a blinded investigator.

Arms

| | |
|------------------------------|------|
| Are arms mutually exclusive? | No |
| Arm title | +cur |

Arm description: -

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Metvix |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Cutaneous use |

Dosage and administration details:

Cutaneous use

| | |
|------------------|------|
| Arm title | -cur |
|------------------|------|

Arm description: -

| | |
|--|---------------|
| Arm type | Experimental |
| Investigational medicinal product name | Metvix |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Cutaneous use |

Dosage and administration details:

Cutaneous use

Notes:

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

Justification: The subjects were not blinded. The treatments were performed by a non blinded investigator. The treatment efficacy evaluations were performed by a blinded investigator.

| Number of subjects in period 1 | +cur | -cur |
|---------------------------------------|------|------|
| Started | 25 | 25 |
| Completed | 25 | 25 |

Baseline characteristics

Reporting groups

| | |
|--------------------------------|------|
| Reporting group title | +cur |
| Reporting group description: - | |
| Reporting group title | -cur |
| Reporting group description: - | |

| Reporting group values | +cur | -cur | Total |
|---|------|------|-------|
| Number of subjects | 25 | 25 | 25 |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 2 | 2 | 2 |
| From 65-84 years | 20 | 20 | 20 |
| 85 years and over | 3 | 3 | 3 |
| Gender categorical Units: Subjects | | | |
| Female | 0 | 0 | 0 |
| Male | 25 | 25 | 25 |

End points

End points reporting groups

| | |
|--------------------------------|------|
| Reporting group title | +cur |
| Reporting group description: - | |
| Reporting group title | -cur |
| Reporting group description: - | |

Primary: Clearance rate 3 months after treatment.

| | |
|--|--|
| End point title | Clearance rate 3 months after treatment. |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| Clearance rate 3 months after treatment. Number of AKs are counted immediately before treatment and 3 months after treatment | |

| End point values | +cur | -cur | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 25 | 25 | | |
| Units: Number | 86 | 84 | | |

Statistical analyses

| | |
|---|--------------------------------|
| Statistical analysis title | Paired t-test |
| Comparison groups | +cur v -cur |
| Number of subjects included in analysis | 50 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[1] |
| P-value | = 0.1 |
| Method | t-test, 2-sided |

Notes:

[1] - There are only 25 subjects in this analysis. 25 subjects in group 1. And the same 25 subjects in group 2. A paired design. Not 50 subjects.

Read our article reporting results in details: <https://doi.org/10.1111/jdv.15744>

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

3 months

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

Dictionary used

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

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

Reporting groups

| | |
|-----------------------|--------------|
| Reporting group title | All subjects |
|-----------------------|--------------|

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: There were no non-serious adverse event found in 5% or more.

| Serious adverse events | All subjects | | |
|---|--|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 5 / 25 (20.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Gastrointestinal disorders | | | |
| Ileus | Additional description: SAE. Treatment and event is not related. | | |
| subjects affected / exposed | 1 / 25 (4.00%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Fistel | | | |
| subjects affected / exposed | 1 / 25 (4.00%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cancer surgery | Additional description: Rectum cancer surgery | | |
| subjects affected / exposed | 1 / 25 (4.00%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Infection | Additional description: SAE. Treatment and event is not related | | |
| subjects affected / exposed | 2 / 25 (8.00%) | | |
| 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 | All subjects | | |
| Total subjects affected by non-serious adverse events subjects affected / exposed | 0 / 25 (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