



Clinical trial results:

Effect of a preinterventional calorie restriction on renal function after contrast agent exposition in patients at risk.

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2012-003696-18 |
| Trial protocol | DE |
| Global end of trial date | 07 October 2016 |

Results information

| | |
|-----------------------------------|--|
| Result version number | v1 (current) |
| This version publication date | 26 December 2020 |
| First version publication date | 26 December 2020 |
| Summary attachment (see zip file) | Final_Report_2020-03-12 (CR_KMN_Abschlussbericht_Synopse_V2_2020-03-12.pdf) |

Trial information

Trial identification

| | |
|-----------------------|----------------|
| Sponsor protocol code | uni-koeln-1547 |
|-----------------------|----------------|

Additional study identifiers

| | |
|------------------------------------|----------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01879839 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | DRKS: 00004361 |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | University of Cologne |
| Sponsor organisation address | Albertus-Magnus-Platz, Cologne, Germany, 50923 |
| Public contact | Clinic II Internal Medicine PD. Dr. V Burst, University Hospital of Cologne, 0049 22147897222, volker.burst@uk-koeln.de |
| Scientific contact | Clinic II Internal Medicine PD. Dr. V Burst, University Hospital of Cologne, 0049 22147897222, volker.burst@uk-koeln.de |

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 | 07 October 2016 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 07 October 2016 |
| Global end of trial reached? | Yes |
| Global end of trial date | 07 October 2016 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The intention of this trial is to investigate, if a short-term calorie restriction before contrast agent administration can prevent contrast induced nephropathy.

Protection of trial subjects:

Increase of creatinine in serum [mg/dl] 48 h after coronary intervention compared with creatinine in serum on day 0 before intervention

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 10 July 2013 |
| 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 | Germany: 80 |
| Worldwide total number of subjects | 80 |
| EEA total number of subjects | 80 |

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 | 73 |
| 85 years and over | 2 |

Subject disposition

Recruitment

Recruitment details:

First patient in: 10.07.2013

Last patient out: 07.10.2016

Pre-assignment

Screening details:

Inclusion: Patients with planned coronary intervention and following diagnosis: pAVK, Creatinine >1,1 (m)/>0,9 (w), diabetes, heart failure with NYHA 3-4, signed consent

Exclusion: end stage kidney failure, kidney transplantation, underweight or obese, infection, allergy on ingredients of formula-diet, participation on another clinical trials

Period 1

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

Arms

| | |
|------------------------------|----------|
| Are arms mutually exclusive? | Yes |
| Arm title | Diet arm |

Arm description:

Patients will receive special nutrition 4 days before the coronary intervention (day -4 till breakfast of day -1), afterwards fasting till coronary intervention on day 0.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | Fresubin® energy fibre Drink (Fresenius Kabi Deutschland GmbH, Bad Homburg, Deutschland). |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral liquid |
| Routes of administration | Oral use |

Dosage and administration details:

Patients get Fresubin® energy fibre Drink for three days vor intervention and morning of day -1 (from day -4 till morning of day -1)

| | |
|--|------------------------|
| Investigational medicinal product name | Accupaque™ |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intravenous bolus use |

Dosage and administration details:

Dosage and administration according standard care of department III of University Hospital of Cologne

| | |
|------------------|-------------|
| Arm title | Control Arm |
|------------------|-------------|

Arm description:

Patients will allowed to eat ad libitum, they have any changes in their eating habits

| | |
|--|------------------------|
| Arm type | comparator |
| Investigational medicinal product name | Accupaque™ |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intravenous bolus use |

Dosage and administration details:

Dosage and administration according standard care of department III of University Hospital of Cologne

| Number of subjects in period 1 | Diet arm | Control Arm |
|---------------------------------------|----------|-------------|
| Started | 40 | 40 |
| Completed | 40 | 40 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|---------------|
| Reporting group title | overall trial |
|-----------------------|---------------|

Reporting group description: -

| Reporting group values | overall trial | Total | |
|------------------------|---------------|-------|--|
| Number of subjects | 80 | 80 | |
| Age categorical | | | |
| Units: Subjects | | | |
| Adults (18-64 years) | 5 | 5 | |
| From 65-84 years | 73 | 73 | |
| 85 years and over | 2 | 2 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 20 | 20 | |
| Male | 60 | 60 | |

End points

End points reporting groups

| | |
|--|-------------|
| Reporting group title | Diet arm |
| Reporting group description: Patients will receive special nutrition 4 days before the coronary intervention (day -4 till breakfast of day -1), afterwards fasting till coronary intervention on day 0. | |
| Reporting group title | Control Arm |
| Reporting group description: Patients will allowed to eat ad libitum, they have any changes in their eating habits | |

Primary: Increase of creatinine in serum 48 h after coronary intervention (exposure of contrast agent)

| | |
|---|--|
| End point title | Increase of creatinine in serum 48 h after coronary intervention (exposure of contrast agent) |
| End point description: | |
| End point type | Primary |
| End point timeframe: 48 h after coronary intervention (exposure of contrast agent) | |

| End point values | Diet arm | Control Arm | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 34 | 33 | | |
| Units: mg/dl | | | | |
| arithmetic mean (standard deviation) | 0.078 (± 0.35) | 0.127 (± 0.21) | | |

Statistical analyses

| | |
|--|---|
| Statistical analysis title | ANCOVA with Covariate Baseline-Creatinine |
| Statistical analysis description: The difference between serum creatinine 48h after the start of coronary intervention (contrast medium exposure) and serum creatinine on Day 0 before intervention is compared in the two trial groups by means of ANCOVA (baseline adjustment) in the ITT population. A PP analysis is also performed. Missing values were replaced with a last-observation-carried-forward approach. | |
| Comparison groups | Diet arm v Control Arm |
| Number of subjects included in analysis | 67 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.49 |
| Method | ANCOVA |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

10.07.2013-07.10.2016

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

Dictionary used

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

| | |
|--------------------|----|
| Dictionary version | 19 |
|--------------------|----|

Reporting groups

| | |
|-----------------------|------------|
| Reporting group title | Diet Group |
|-----------------------|------------|

Reporting group description: -

| | |
|-----------------------|---------------|
| Reporting group title | Control Group |
|-----------------------|---------------|

Reporting group description: -

| Serious adverse events | Diet Group | Control Group | |
|---|---|----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 40 (2.50%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | | | |
| Cardiac disorders | | | |
| Coronary artery disease | Additional description: Progression coronary artery disease | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 40 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac Ischemia | Additional description: Cardiac Ischemia | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 40 (2.50%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 1 %

| Non-serious adverse events | Diet Group | Control Group | |
|---|------------------|-----------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 17 / 40 (42.50%) | 9 / 40 (22.50%) | |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|--|---------------------|--|
| Groin hematoma subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 1 / 40 (2.50%) 1 | |
| Lateral hematoma | Additional description: Lateral hematoma next to puncture site of cardiac catheter | | |
| subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 0 / 40 (0.00%) 0 | |
| Vascular disorders | | | |
| Circulatory collapse subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 0 / 40 (0.00%) 0 | |
| Orthostatis dysregulation subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 0 / 40 (0.00%) 0 | |
| Cardiac disorders | | | |
| Angina Pectoris subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 1 / 40 (2.50%) 1 | |
| Hypertension subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 1 / 40 (2.50%) 1 | |
| Hypotension subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 2 / 40 (5.00%) 2 | |
| Tachyarrhythmia absoluta subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 0 / 40 (0.00%) 0 | |
| Thoracic pain subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 0 / 40 (0.00%) 0 | |
| Blood and lymphatic system disorders | | | |
| Hematoma subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 0 / 40 (0.00%) 0 | |
| General disorders and administration site conditions | | | |
| Unclear pain | | | |

| | | | |
|--|---------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 1 / 40 (2.50%) 1 | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 40 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Nausea | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 40 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Thoracic pain rear sternum | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 40 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Numbness in right arm | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 40 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Numbness in right middel finger | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 40 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Numbness in right thigh | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 40 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Numbness in right leg | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 40 (2.50%) | |
| occurrences (all) | 0 | 1 | |
| Sensivity disorder in right leg | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 40 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 2 / 40 (5.00%) | |
| occurrences (all) | 3 | 2 | |
| Hypokaliemia | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 40 (0.00%) | |
| occurrences (all) | 1 | 0 | |

| | | | |
|--|---------------------|---------------------|--|
| Endocrine disorders Hyperglycemia subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 0 / 40 (0.00%) 0 | |
| Infections and infestations Urinary tract infection subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 0 / 40 (0.00%) 0 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-----------------|---|
| 13 October 2015 | Prolongation of study period because trial participations number was not reached in planned time. |

Notes:

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.

| |
|---|
| There are any limitations and caveats during study period |
|---|

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/29535139>