



Clinical trial results:

Breast lesion detection and characterization at contrast-Enhanced MRI of the breast: comparison of gadoterate meglumine versus gadobenate dimeglumine at 3 Tesla

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2011-005498-21 |
| Trial protocol | AT |
| Global end of trial date | 25 January 2017 |

Results information

| | |
|--------------------------------|-------------------|
| Result version number | v1 (current) |
| This version publication date | 30 September 2020 |
| First version publication date | 30 September 2020 |

Trial information

Trial identification

| | |
|-----------------------|----|
| Sponsor protocol code | NA |
|-----------------------|----|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Bracco |
| Sponsor organisation address | Via Caduti di Marcinelle 13, Milano, Italy, 20134 |
| Public contact | Medical University of Vienna, Medical University of Vienna, 0043 4040048200, thomas.helbich@meduniwien.ac.at |
| Scientific contact | Medical University of Vienna, Medical University of Vienna, thomas.helbich@meduniwien.ac.at |

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 | 24 August 2018 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 15 December 2016 |
| Global end of trial reached? | Yes |
| Global end of trial date | 25 January 2017 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The aim of this study is to intraindividually compare the use of gadobenate dimeglumine (MultiHance, Bracco Imaging, Milan, Italy) and gadoterate meglumine (DOTAREM, Guerbet, France) for breast MR imaging by using a prospective study design, evaluated independently by blinded readers.

Protection of trial subjects:

insurance, patient informed consents

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 16 November 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 | Austria: 104 |
| Worldwide total number of subjects | 104 |
| EEA total number of subjects | 104 |

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) | 100 |
| From 65 to 84 years | 4 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

consecutive women presenting for the assessment of abnormal breast imaging findings (ie, classified as BI-RADS 0, 4, or 5) on mammography, tomosynthesis, or ultrasound were eligible for this study. Excluded women below 18 years of age, women who were pregnant or lactating or treatment of breast, contraindication to MRI

Pre-assignment

Screening details:

Consecutive women presenting for the assessment of abnormal breast imaging findings (ie, classified as BI-RADS 0, 4, or 5) on mammography, tomosynthesis, or ultrasound were eligible for this study. Excluded women below 18 years of age, women who were pregnant or lactating or treatment of breast, contraindication to MRI

Pre-assignment period milestones

| | |
|------------------------------|-----|
| Number of subjects started | 104 |
| Number of subjects completed | 104 |

Period 1

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

Blinding implementation details:

Each reader was blinded to all clinical and radiological information.

Arms

| | |
|--|--|
| Arm title | comparison |
| Arm description: - | |
| Arm type | Active comparator |
| Investigational medicinal product name | gadobenate |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Concentrate and solvent for solution for injection |
| Routes of administration | Intravenous bolus use |

Dosage and administration details:

0,0075mmol/kg

| | |
|---------------------------------------|------------|
| Number of subjects in period 1 | comparison |
| Started | 104 |
| Completed | 104 |

Baseline characteristics

Reporting groups

| | |
|--------------------------------|---------------|
| Reporting group title | overall trial |
| Reporting group description: - | |

| Reporting group values | overall trial | Total | |
|--|---------------|-------|--|
| Number of subjects | 104 | 104 | |
| 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) | 100 | 100 | |
| From 65-84 years | 4 | 4 | |
| 85 years and over | 0 | 0 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 104 | 104 | |
| Male | 0 | 0 | |

Subject analysis sets

| | |
|----------------------------|--------------|
| Subject analysis set title | CE-MRI |
| Subject analysis set type | Per protocol |

Subject analysis set description:

The analysis was performed on a per-breast basis; thus, the accuracy of L-CEM vs. CE-MRI to analyze multifocality or multicentricity was not assessed.

| | |
|----------------------------|--------------|
| Subject analysis set title | CEM |
| Subject analysis set type | Per protocol |

Subject analysis set description:

The analysis was performed on a per-breast basis; thus, the accuracy of L-CEM vs. CE-MRI to analyze multifocality or multicentricity was not assessed.

| Reporting group values | CE-MRI | CEM | |
|--|--------|-----|--|
| Number of subjects | 104 | 104 | |
| 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) | 100 | 100 | |
| From 65-84 years | 4 | 4 | |
| 85 years and over | 0 | 0 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 104 | 104 | |
| Male | 0 | 0 | |

End points

End points reporting groups

| | |
|---|--------------|
| Reporting group title | comparison |
| Reporting group description: - | |
| Subject analysis set title | CE-MRI |
| Subject analysis set type | Per protocol |
| Subject analysis set description: The analysis was performed on a per-breast basis; thus, the accuracy of L-CEM vs. CE-MRI to analyze multifocality or multicentricity was not assessed. | |
| Subject analysis set title | CEM |
| Subject analysis set type | Per protocol |
| Subject analysis set description: The analysis was performed on a per-breast basis; thus, the accuracy of L-CEM vs. CE-MRI to analyze multifocality or multicentricity was not assessed. | |

Primary: Comparison

| | |
|----------------------------|------------|
| End point title | Comparison |
| End point description: | |
| End point type | Primary |
| End point timeframe: na | |

| End point values | CE-MRI | CEM | | |
|----------------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 104 | 104 | | |
| Units: number of lesions | | | | |
| number (confidence interval 95%) | 93.6 (86.5 to 97.0) | 91.4 (84.1 to 95.5) | | |

Statistical analyses

| | |
|---|--------------|
| Statistical analysis title | accuracy |
| Statistical analysis description: The analysis was performed on a per-breast basis; thus, the accuracy of L-CEM vs. CE-MRI to analyze multifocality or multicentricity was not assessed. | |
| Comparison groups | CE-MRI v CEM |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 208 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| P-value | < 0.05 |
| Method | Wilcoxon (Mann-Whitney) |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

1 day

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 10.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--------------|
| Reporting group title | all subjects |
|-----------------------|--------------|

Reporting group description: -

| Serious adverse events | all subjects | | |
|---|-----------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 104 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

Frequency threshold for reporting non-serious adverse events: 4 %

| Non-serious adverse events | all subjects | | |
|---|-----------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1 / 104 (0.96%) | | |
| Skin and subcutaneous tissue disorders | | | |
| urticria | | | |
| alternative dictionary used: MedDRA 10.0 | | | |
| subjects affected / exposed | 1 / 104 (0.96%) | | |
| occurrences (all) | 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.

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|----|
| NA |
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Notes: