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.

NA

Notes: