Clinical trial results:
Matrix-associated autologous chrondrocyte transplantation for grade four cartilage lesions of the knee joint - clinical and radiological outcome in correlation to the initial cell count of the chondrocyte graft

Summary

EudraCT number	2015-003584-11
Trial protocol	AT
Global end of trial date	12 May 2020

Results information

Result version number	v1 (current)
This version publication date	13 December 2021
First version publication date	13 December 2021

Trial information

Trial identification

Sponsor protocol code	MACT-IBK-2015

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University Innsbruck
Sponsor organisation address	Christoph-Probst-Platz 1, Innrain 52, Innsbruck, Austria, 6020
Public contact	Dr. Eichinger Martin, Univ.-Klinik für Orthopädie und Traumatologie Anichstraße 35 6020 Innnsbruck, 0043 51250422821, martin.eichinger@tirol-kliniken.at
Scientific contact	Dr. Eichinger Martin, Univ.-Klinik für Orthopädie und Traumatologie Anichstraße 35 6020 Innnsbruck, 0043 51250422821, martin.eichinger@tirol-kliniken.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	12 May 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 May 2016
Global end of trial reached?	Yes
Global end of trial date	12 May 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this study is to evaluate the clinical and radiological outcome (MRT) after MACT and to correlate these findings with the initial cell count of the chondrocyte graft. What is more, further knowledge about additional factors influencing the outcome of the surgery may be gained. This pilot study could provide valuable data for the design of a prospective randomized clinical trial.

Protection of trial subjects:

Die Magnetresonanztomographie (MRT) des Kniegelenkes entspricht der auch routinemäßig angewendeten MRT-Untersuchung. Bei dieser Untersuchung werden in den im Magnetfeld liegenden Körper (mindestens 1.5 Tesla) Radiowellen mit einer Frequenz von ca. 63.5 MHz gesendet. Schädliche Auswirkungen auf den menschlichen Körper sind bisher nicht bekannt geworden und aufgrund der geringen Energie der Radiowellen auch nicht anzunehmen.

Background therapy:

Bei dieser Patientenpopulation ist keine Dauerbehandlung/Dauermedikation vorgesehen.

Evidence for comparator:

Es gibt für diese Fragestellung keinen Komparator.

Actual start date of recruitment	01 October 2015
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	Austria: 28
Worldwide total number of subjects	28
EEA total number of subjects	28

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	28
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

In der Universitätsklinik für Unfallchirurgie wurden seit 2006, 64 Patienten mittels MACT behandelt und entsprechend einem standardisierten Protokoll nachbehandelt. Aus diesem Patientenkollektiv wurden retrospektiv alle Patienten, die den Einschlusskriterien entsprechen, ausgewählt.

Pre-assignment

Screening details:

Von den 64 Patienten wurden 42 Patienten gescreent, wovon letztendlich 28 Patienten in die Studie eingeschlossen werden konnten.

Period 1

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

Arms

Arm title	Behandlungsarm

Arm description:

Inhalt dieser Studie ist die Beurteilung der Gelenksfläche nach matrix-assoziierter Chondrozytentransplantation mittels Magnetresonanztomographie sowie die Erhebung von klinischen Daten mittels einer Routineuntersuchung und mittels Patienten-Fragebögen.

Arm type	Experimental
Investigational medicinal product name	ATMP-Matrix associated autologous chondrocyte transplantation
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Implantation matrix
Routes of administration	Implantation

Dosage and administration details:

Das ATMP wurde einmalig während der chirurgischen Versorgung implantiert.

Number of subjects in period 1	Behandlungsarm
Started	28
Completed	27
Not completed	1
Consent withdrawn by subject	1

Baseline characteristics

Reporting groups	
Reporting group title	Behandlung

Reporting group description: -

Reporting group values	Behandlung	Total	
Number of subjects	28	28	
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)	28	28	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	38		
standard deviation	± 11	-	
Gender categorical Units: Subjects			
Female	8	8	
Male	20	20	

End points

End points reporting groups

Reporting group title	Behandlungsarm

Reporting group description:

Inhalt dieser Studie ist die Beurteilung der Gelenksfläche nach matrix-assoziierter Chondrozytentransplantation mittels Magnetresonanztomographie sowie die Erhebung von klinischen Daten mittels einer Routineuntersuchung und mittels Patienten-Fragebögen.

Primary: Radiologisches outcome: Defektfüllung

End point title	Radiologisches outcome: Defektfüllung[1]

End point description:

End point type	Primary

End point timeframe:

Tag 1 (MRT Untersuchung)

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: Statistische Analysen wurden auf Grund der geringen Datenmenge nicht durchgeführt.

End point values	Behandlungsarm			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: number				
number (not applicable)				
Komplette Füllung	23			
Inkomplette Füllung	4			

Statistical analyses

No statistical analyses for this end point

Primary: Radiologisches outcome: Signalintensität des Ersatzgewebes bei Dual T2-FSE

End point title	Radiologisches outcome: Signalintensität des Ersatzgewebes bei Dual T2-FSE[2]

End point description:

End point type	Primary

End point timeframe:

Tag 1 (MRT Untersuchung)

Notes:

[2] - 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: Statistische Analysen wurden auf Grund der geringen Datenmenge nicht durchgeführt.

End point values	Behandlungsarm			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: number				
number (not applicable)				
Isointens	16			
Moderat hyperintens	8			
Nicht beurteilbar	1			
Nicht beurteilt	2			

Statistical analyses

No statistical analyses for this end point

Primary: Radiologisches outcome: Erguss

End point title	Radiologisches outcome: Erguss[3]

End point description:

End point type	Primary

End point timeframe:

Tag 1 (MRT Untersuchung)

Notes:

[3] - 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: Statistische Analysen wurden auf Grund der geringen Datenmenge nicht durchgeführt.

End point values	Behandlungsarm			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: Number				
number (not applicable)				
Erguss	5			
Kein Erguss	19			
Nicht beurteilbar	1			
Nicht beurteilt	2			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Tag 1 der Untersuchung

Assessment type	Systematic

Dictionary used

Dictionary name	CTCAE
Dictionary version	4.3

Reporting groups

Reporting group title	Behandlungsarm

Reporting group description:

Inhalt dieser Studie ist die Beurteilung der Gelenksfläche nach matrix-assoziierter Chondrozytentransplantation mittels Magnetresonanztomographie sowie die Erhebung von klinischen Daten mittels einer Routineuntersuchung und mittels Patienten-Fragebögen.

Serious adverse events	Behandlungsarm		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 27 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Behandlungsarm		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 27 (0.00%)		

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: Im Rahmen der einmaligen Studienvisite sind keine Adverse Events aufgetreten.

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