



Clinical trial results:

Skeletal muscle-derived cell implantation for the treatment of fecal incontinence: a single arm, open label, interventional, follow-up study

Summary

EudraCT number	2021-005399-21
Trial protocol	AT
Global end of trial date	03 April 2024

Results information

Result version number	v1 (current)
This version publication date	27 December 2025
First version publication date	27 December 2025

Trial information

Trial identification

Sponsor protocol code	IC-01-02-2-010
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Innovacell GmbH
Sponsor organisation address	Mitterweg 24, Innsbruck, Austria, 6020
Public contact	Innovacell GmbH, Innovacell GmbH, 0043 512573680, office@innovacell.com
Scientific contact	Innovacell GmbH, Innovacell GmbH, 0043 512573680, office@innovacell.com

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	05 November 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 April 2024
Global end of trial reached?	Yes
Global end of trial date	03 April 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Assessment of safety and efficacy of study treatment

Protection of trial subjects:

This study was conducted in full accordance with the International Conference of Harmonisation Good Clinical Practice (GCP) Consolidated Guideline (E6) and any applicable national and local laws and regulations.

Background therapy:

N/A

Evidence for comparator:

N/A

Actual start date of recruitment	16 October 2023
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: 7
Worldwide total number of subjects	7
EEA total number of subjects	7

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)	3
From 65 to 84 years	4

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

Approximately 10 patients that were planned to be randomized to placebo in STEFFI study (EudraCT 2010-021463-32). Patient recruitment was completed within 1 month. Patients have

Pre-assignment

Screening details:

Eligible patients were identified from the placebo group of the preceding STEFFI study and invited to participate in this follow-up. After signing a new informed consent, patients underwent baseline assessments, received ICEF15 treatment, and attended predefined follow-up visits to evaluate efficacy and safety.

Period 1

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

Blinding implementation details:

not applicable

Arms

Arm title	Treatment Arm
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Arm description:

All patients enrolled in the STEFFI-FU study received treatment with ICEF15, and aSMDC product. The IMP was administered as a single intramuscular injection of $50 \pm 10 \times 10^6$ cells into the external anal sphincter at the treatment/implantation visit

Arm type	Experimental
Investigational medicinal product name	Autologous skeletal muscle-derived cells
Investigational medicinal product code	ICEF15
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

The IMP ($50 \pm 10 \times 10^6$ aSMDC) is stored and transported in 3 x 1 mL cell transportation medium. Each dose of IMP is filled in 3 cryovials. Prior to implantation, IMP is prepared and thawed by addition of 3 x 1 mL Ringer's lactate solution. Total volume of IMP injected for implantation of 6 mL. The IMP was injected (single administration) at Visit 3 into the external anal sphincter of each of each patient using standardized, ultrasound -guided injection tool under analgo sedation (or general anaesthesia, if preferred).

Number of subjects in period 1	Treatment Arm
Started	7
Completed	7

Baseline characteristics

Reporting groups

Reporting group title	Overall Study (overall period)
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Reporting group description: -

Reporting group values	Overall Study (overall period)	Total	
Number of subjects	7	7	
Age categorical			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: years			
arithmetic mean	58.9		
standard deviation	± 17.3	-	
Gender categorical			
Units: Subjects			
Female	7	7	
Male	0	0	

End points

End points reporting groups

Reporting group title	Treatment Arm
Reporting group description: All patients enrolled in the STEFFI-FU study received treatment with ICEF15, and aSMDC product. The IMP was administered as a single intramuscular injection of $50 \pm 10 \times 10^6$ cells into the external anal sphincter at the treatment/implantation visit	

Primary: Absolute change IEF 3 months

End point title	Absolute change IEF 3 months ^[1]
End point description: The frequency of incontinence episodes were documented by a bowel diary that was completed by the patient. In this study, the frequency of incontinence episodes was calculated as the number of incontinence episodes over a period of 2 weeks.	
End point type	Primary
End point timeframe: The primary endpoint of the current study was the incontinence episode frequency at V5 (3 months post implantation) compared to V2 (baseline period).	

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: Due to the limited number of patients included no formal testing has been applied

End point values	Treatment Arm			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: IEF change				
arithmetic mean (standard deviation)	3.25 ($\pm$ 0.5)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Timeframe of reporting adverse event:

16-OCT-2023 to 03-APR-2024

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.1
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Reporting groups

Reporting group title	Treatment Arm
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Reporting group description:

All patients enrolled in the STEFFI-FU study received treatment with ICEF15, and aSMDC product. The IMP was administered as a single intramuscular injection of $50 \pm 10 \times 10^6$ cells into the external anal sphincter at the treatment/implantation visit

Serious adverse events	Treatment Arm		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0.1 %

Non-serious adverse events	Treatment Arm		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 7 (57.14%)		
Cardiac disorders			
Palpitations	Additional description: Possibly related to concomitant Pelvic Floor Electrical Stimulation		
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
General disorders and administration site conditions			
Fatigue	Additional description: Related to IMP - the AE has been reported for 2 patients		
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		
Gastrointestinal disorders			

Rectal spasm subjects affected / exposed occurrences (all)	Additional description: Related to concomitant Pelvic Floor Electrical Stimulation		
	1 / 7 (14.29%)		
	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.

None reported

Notes: