# Clinical trial results:
# Clinical assessment of the tissue distribution of [18F]FMISO, INJ SOL after intravenous injection in patiens with malignancy

## Summary

| | |
|---|---|
| EudraCT number | 2011-000839-84 |
| Trial protocol | CZ |
| Global end of trial date | 20 June 2014 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 29 August 2021 |
| First version publication date | 29 August 2021 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | FMISO/2011/II |

**Additional study identifiers**

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

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | RadioMedic s.r.o. |
| Sponsor organisation address | Husinec-Řež 289, Řež, Czechia, 250 68 |
| Public contact | Publicly available information service for professionals VPOIS, RadioMedic s.r.o., +420 725015370, verejnost@radiomedic.cz |
| Scientific contact | Publicly available information service for professionals VPOIS, RadioMedic s.r.o., +420 725015370, verejnost@radiomedic.cz |

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 January 2015 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 20 June 2014 |
| Global end of trial reached? | Yes |
| Global end of trial date | 20 June 2014 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The main objective of the clinical trial is to confirm the accumulation of [18F]FMISO, INJ SOL in squamous cell tumors, in accordance with the results of non-clinical studies and published data, and thus to prove the diagnostic potential of [18F]FMISO, INJ SOL in nuclear medicine.
Furthermore, the trial aims to verify whether the administered radioactivity is sufficient to obtain well evaluable PET images under given conditions.
The trial should also confirm that parenteral administration of [18F]FMISO, INJ SOL does not cause any adverse drug reactions, including allergic reactions.

Protection of trial subjects:

The conduct of this clinical study met all local legal and regulatory requirements. The study was conducted in accordance with the ethical principles of Good Clinical Practice (GCP) and the Declaration of Helsinki. Participating subjects signed informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. The study was regularly monitored by the Sponsor.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 30 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 | Czechia: 16 |
| Worldwide total number of subjects | 16 |
| EEA total number of subjects | 16 |

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) | 6 |
| From 65 to 84 years | 10 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Screening performed by a medical doctor according to the inclusion and exclusion criteria.
Main screening criteria:
Squamous cell carcinoma confirmed by 18F-FDG PET and histologic examination
18F-FDG PET examination performed within 28 days
Laboratory blood test (CBC, serum creatinine, urea, HCG pregnancy test) and urinalysis

### Period 1

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

### Arms

| | |
|---|---|
| **Arm title** | [18F]FMISO PET |

Arm description: -

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | [18F]FMISO, INJ SOL |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Single dose administration, 4.5 MBq/kg (maximal dose 550 MBq) of [18F]FMISO, INJ SOL 2-3 hours prior to PET scan

| **Number of subjects in period 1** | [18F]FMISO PET |
|---|---|
| Started | 16 |
| Completed | 15 |
| Not completed | 1 |
| reclassification of histological findings | 1 |

## Baseline characteristics

### Reporting groups

| Reporting group title | Overall trial |
|---|---|

Reporting group description: -

| Reporting group values | Overall trial | Total | |
|---|---|---|---|
| Number of subjects | 16 | 16 | |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 6 | 6 | |
| From 65-84 years | 10 | 10 | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 13 | 13 | |
| Male | 3 | 3 | |

### Subject analysis sets

| Subject analysis set title | Full analysis set |
|---|---|
| Subject analysis set type | Full analysis |

Subject analysis set description:
Includes all patients who entered the study.

| Reporting group values | Full analysis set | | |
|---|---|---|---|
| Number of subjects | 16 | | |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 6 | | |
| From 65-84 years | 10 | | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 13 | | |
| Male | 3 | | |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | [18F]FMISO PET |
| Reporting group description: - | |
| Subject analysis set title | Full analysis set |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Includes all patients who entered the study. | |

### Primary: Efficacy - Accumulation of [18F]FMISO, INJ SOL in the tumor

| | |
|---|---|
| End point title | Efficacy - Accumulation of [18F]FMISO, INJ SOL in the tumor[1] |
| End point description: | |
| PET scan was performed 2-3 hours after [18F]FMISO, INJ SOL administration with subsequent semi-quantitative evaluation of [18F]FMISO accumulation using the maximal standardized uptake value (SUVmax) in the region of interest (ROI). The SUVmax values ranged from 2.4 to 5.9 and confirmed accumulation of [18F]FMISO in squamous cell tumors. | |
| End point type | Primary |
| End point timeframe: | |
| - evaluation of individual results for each single patient within 48 hours after [18F]FMISO, INJ SOL PET scan<br>- statistical processing of results (descriptive statistics only) after the end of trial | |
| 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.<br>Justification: Single arm study, only descriptive statistics were performed for this endpoint. | |

| End point values | Full analysis set | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 15 | | | |
| Units: SUVmax | | | | |
| arithmetic mean (standard deviation) | 3.71 (± 1.08) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Comparison of [18F]FMISO, INJ SOL and 18F-FDG accumulation

| | |
|---|---|
| End point title | Comparison of [18F]FMISO, INJ SOL and 18F-FDG accumulation |
| End point description: | |
| For each patient 18F-FDG PET scan was performed on the same device using the same procedure within 28 days prior to [18F]FMISO, INJ SOL PET scan. Semi-quantitative evaluation based on ratio of maximal standardized uptake value (SUVmax) in the region of interest (ROI) of [18F]FMISO, INJ SOL and 18F-FDG was performed. The differences in SUVmax values between FMISO and FDG reflect a different mechanism of accumulation. | |
| End point type | Secondary |
| End point timeframe: | |
| - evaluation of individual results for each single patient within 48 hours after [18F]FMISO, INJ SOL PET scan | |

- statistical processing of results after the end of trial

| End point values | Full analysis set | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 15 | | | |
| Units: ratio of SUVmax FDG/FMISO | | | | |
| arithmetic mean (standard deviation) | 5.56 (± 2.72) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Evaluation of changes in physiological functions in relation to [18F]FMISO, INJ SOL administration

| End point title | Evaluation of changes in physiological functions in relation to [18F]FMISO, INJ SOL administration |
|---|---|

End point description:

Evaluation of changes in physiological functions in relation to [18F]FMISO, INJ SOL administration included measurement of systolic and diastolic blood pressure and heart rate before and after application. Changes in patients' subjective feelings were also monitored.
The observed changes in function were not clinically significant and no patient reported a change in subjective feelings associated with the clinical trial.

| End point type | Secondary |
|---|---|

End point timeframe:

- evaluation of acute changes within 2 hours after examination
- statistical processing of results (descriptive statistics only) after the end of trial

| End point values | Full analysis set | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 15 | | | |
| Units: HRbefore-HRafter (bpm) | | | | |
| arithmetic mean (standard deviation) | 1.93 (± 6.81) | | | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

| Adverse events information[1] | |
|---|---|
| Timeframe for reporting adverse events: | |
| Adverse events recorded from clinical trial enrollment (signing an informed consent) until hospital discharge. | |
| Assessment type | Systematic |

| Dictionary used | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 14.1 |

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

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: [18F]FMISO is a radiolabeled imaging agent used in such low chemical doses that do not exhibit clinically and/or analytically noticeable pharmacodynamic effects. Chemical amount of FMISO in single injection dose of [18F]FMISO with administrated activity 400MBq is approximately 1,5.10-9 g.

## 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