



## Clinical trial results:

### Impact de la TEP dans la stratégie diagnostique des fièvres d'origine indéterminée ou des syndromes inflammatoires nus chez l'adulte immunocompétent.

#### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2007-005823-14 |
| Trial protocol           | FR             |
| Global end of trial date | 01 May 2013    |

#### Results information

|                                   |  |
|-----------------------------------|--|
| Result version number             | v1 (current)   |
| This version publication date     | 04 June 2021   |
| First version publication date    | 04 June 2021   |
| Summary attachment (see zip file) | statistical report (FUO-TEP Rapport Statistique SD 20190730.pdf) |

#### Trial information

##### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | I07005 |
|-----------------------|--------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT01200771 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | Limoges University Hospital  |
| Sponsor organisation address | 2 avenue Martin Luther King, LIMOGES, France, 87042                          |
| Public contact               | Pr Kim LY, Limoges University Hospital, +33 555058076, kim.ly@chu-limoges.fr |
| Scientific contact           | Pr Kim LY, Limoges University Hospital, +33 555058076, kim.ly@chu-limoges.fr |

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:

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**Results analysis stage**

|  |                  |
|--|------------------|
| Analysis stage                                       | Interim          |
| Date of interim/final analysis                       | 21 December 2015 |
| Is this the analysis of the primary completion data? | Yes              |
| Primary completion date                              | 01 May 2013      |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 01 May 2013      |
| Was the trial ended prematurely?                     | No               |

Notes:

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**General information about the trial**

Main objective of the trial:

Evaluer la rentabilité diagnostique de la TEP (proportion de patients chez qui le diagnostic étiologique est réalisé grâce à la TEP), réalisé précocement, chez un groupe de patients présentant une fièvre prolongée d'origine indéterminée (FUO) ou un syndrome inflammatoire nu.

Protection of trial subjects:

Non protection specific

Background therapy: -

Evidence for comparator: -

|   |             |
|---|-------------|
| Actual start date of recruitment                          | 30 May 2008 |
| Long term follow-up planned                               | No          |
| Independent data monitoring committee (IDMC) involvement? | No          |

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

|                                      |             |
|--------------------------------------|-------------|
| Country: Number of subjects enrolled | France: 111 |
| Worldwide total number of subjects   | 111         |
| EEA total number of subjects         | 111         |

Notes:

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**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)                      | 65 |
| From 65 to 84 years                       | 44 |
| 85 years and over                         | 2  |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

no pre-assignment period

### Period 1

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

### Arms

|           |              |
|-----------|--------------|
| Arm title | all patients |
|-----------|--------------|

Arm description: -

|  |                        |
|--|------------------------|
| Arm type                               | Experimental           |
| Investigational medicinal product name | 18FDG                  |
| Investigational medicinal product code |                        |
| Other name                             |                        |
| Pharmaceutical forms                   | Solution for injection |
| Routes of administration               | Intravenous use        |

Dosage and administration details:

Dosage and administration followed the SPCs

| Number of subjects in period 1 | all patients |
|--------------------------------|--------------|
| Started                        | 111          |
| Completed                      | 103          |
| Not completed                  | 8            |
| secondary exclusion            | 8            |

## Baseline characteristics

### Reporting groups

|                       |               |
|-----------------------|---------------|
| Reporting group title | overall study |
|-----------------------|---------------|

Reporting group description: -

| Reporting group values | overall study | Total |  |
|------------------------|---------------|-------|--|
| Number of subjects     | 111           | 111   |  |
| Age categorical        |               |       |  |
| Units: Subjects        |               |       |  |
| Adults (18-64 years)   | 65            | 65    |  |
| From 65-84 years       | 44            | 44    |  |
| 85 years and over      | 2             | 2     |  |
| Age continuous         |               |       |  |
| Units: years           |               |       |  |
| median                 | 58.2          |       |  |
| standard deviation     | ± 16.7        | -     |  |
| Gender categorical     |               |       |  |
| Units: Subjects        |               |       |  |
| Female                 | 52            | 52    |  |
| Male                   | 59            | 59    |  |

### Subject analysis sets

|                            |              |
|----------------------------|--------------|
| Subject analysis set title | all patients |
|----------------------------|--------------|

|                           |                    |
|---------------------------|--------------------|
| Subject analysis set type | Intention-to-treat |
|---------------------------|--------------------|

Subject analysis set description:  
patients with TEP and scanner

| Reporting group values | all patients |  |  |
|------------------------|--------------|--|--|
| Number of subjects     | 103          |  |  |
| Age categorical        |              |  |  |
| Units: Subjects        |              |  |  |
| Adults (18-64 years)   | 61           |  |  |
| From 65-84 years       | 41           |  |  |
| 85 years and over      | 1            |  |  |
| Age continuous         |              |  |  |
| Units: years           |              |  |  |
| median                 | 58.2         |  |  |
| standard deviation     | ± 16.7       |  |  |
| Gender categorical     |              |  |  |
| Units: Subjects        |              |  |  |
| Female                 | 50           |  |  |
| Male                   | 53           |  |  |

## End points

### End points reporting groups

|                                   |                    |
|-----------------------------------|--------------------|
| Reporting group title             | all patients       |
| Reporting group description: -    |                    |
| Subject analysis set title        | all patients       |
| Subject analysis set type         | Intention-to-treat |
| Subject analysis set description: |                    |
| patients with TEP and scanner     |                    |

### Primary: Assess the contribution of FDG-PET/CT in the early diagnostic work-up of patients with FUO or chronic inflammatory syndrome

|                 |  |
|-----------------|--|
| End point title | Assess the contribution of FDG-PET/CT in the early diagnostic work-up of patients with FUO or chronic inflammatory syndrome <sup>[1]</sup> |
|-----------------|--|

End point description:

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

3 month

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: see statistical report joined

|                             |                 |  |  |  |
|-----------------------------|-----------------|--|--|--|
| <b>End point values</b>     | all patients    |  |  |  |
| Subject group type          | Reporting group |  |  |  |
| Number of subjects analysed | 103             |  |  |  |
| Units: number               | 20              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

overall study

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 15.1 |
|--------------------|------|

### Reporting groups

|                       |              |
|-----------------------|--------------|
| Reporting group title | all patients |
|-----------------------|--------------|

Reporting group description: -

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: no EA recotled for this study, only SAE

| Serious adverse events  | all patients    |  |  |
|---|-----------------|--|--|
| Total subjects affected by serious adverse events                   |                 |  |  |
| subjects affected / exposed   | 7 / 103 (6.80%) |  |  |
| number of deaths (all causes)                                       | 2               |  |  |
| number of deaths resulting from adverse events                      | 2               |  |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                 |  |  |
| Acute myeloid leukaemia   |                 |  |  |
| subjects affected / exposed   | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all                     | 0 / 1           |  |  |
| deaths causally related to treatment / all                          | 0 / 1           |  |  |
| Injury, poisoning and procedural complications                      |                 |  |  |
| Wrist fracture  |                 |  |  |
| subjects affected / exposed   | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all                     | 0 / 1           |  |  |
| deaths causally related to treatment / all                          | 0 / 0           |  |  |
| Nervous system disorders  |                 |  |  |
| Headache coma hemiplegia  |                 |  |  |
| subjects affected / exposed   | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all                     | 0 / 1           |  |  |
| deaths causally related to treatment / all                          | 0 / 0           |  |  |
| headache vomiting   |                 |  |  |

|  |                 |  |  |
|--|-----------------|--|--|
| subjects affected / exposed                          | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |
| General disorders and administration site conditions |                 |  |  |
| Death  |                 |  |  |
| subjects affected / exposed                          | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1           |  |  |
| deaths causally related to treatment / all           | 0 / 1           |  |  |
| Respiratory, thoracic and mediastinal disorders      |                 |  |  |
| Respiratory distress                                 |                 |  |  |
| subjects affected / exposed                          | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |
| Infections and infestations                          |                 |  |  |
| Septic shock   |                 |  |  |
| subjects affected / exposed                          | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |

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

|   |                 |  |  |
|---|-----------------|--|--|
| <b>Non-serious adverse events</b>                     | all patients    |  |  |
| Total subjects affected by non-serious adverse events |                 |  |  |
| subjects affected / exposed                           | 0 / 103 (0.00%) |  |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date           | Amendment   |
|----------------|---|
| 03 August 2010 | prolongation of inclusion period  |
| 20 June 2011   | prolongation of inclusion period<br>increasing of inclusion number<br>update of patient following |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported