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TRAPIST Add a subject Subjects Queries Overdue forms

TRAP Intervention Study



21 Apr 2016 20:47 UTC | TRAPIST 1.0.0-RC2 | Red Pill 11.0.6



Add subject + date study entry

FW: Confidential: new account details - lewiliesbeth@gmail.com - Gmail

TRAPIST | Add Study entry | Subject

+

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TRAPIST

Add a subject

Subjects

Queries

Overdue forms

Study entry

Enter the patient identifier and the date of entry to the study

Study entry

Identifier*

Date of study entry*

21/04/2016

dd/mm/yyyy

Notes

Save form

* required

Add subject + date study entry + save

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TRAPIST | View Study entry | Subject LEL

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TRAPIST | Add a subject | Subjects | Queries | Overdue forms

Subject ID LEL | Date entered study: 21 Apr 2016 | 1: UZLeuven, Belgium

Return to subject

Add General information

Jump to form ...

+

Create a query

Study entry

Enter the patient identifier and the date of entry to the study

This form was saved.

This form was created at 21 Apr 2016 20:49 UTC by Liesbeth Lewi (ID 1994 - Investigator at UZLeuven)

Study entry

Identifier

LEL

Date of study entry

21/04/2016

dd/mm/yyyy

Notes

-

21 Apr 2016 20:49 UTC | TRAPIST 1.0.0-RC2 | Red Pill 11.0.6

Date of birth + EDD + save

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TRAPIST | Add General information | Subject LEL

+

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TRAPIST | Add a subject | Subjects | Queries | Overdue forms

Subject ID LEL | Date entered study: 21 Apr 2016 | 1: UZLeuven, Belgium

Return to subject

General information

Draft saved

General information prior to randomisation

Patient's initials *

LEL

Patient's date of birth *

09/02/1971

dd/mm/yyyy

Estimated due date *

18/10/2016

dd/mm/yyyy

Notes

Save form

* required

21 Apr 2016 20:49 UTC | TRAPIST 1.0.0-RC2 | Red Pill 11.0.6

Subjects-> Subject Details -> click randomisation

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TRAPIST | Subjects

+

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TRAPIST

Add a subject

Subjects

Queries

Overdue forms

Subjects

Search:

Subject ID	Site	Randomisation group	Date randomised	Status
12	UZLeuven	Early Intervention	16 Apr 2016 17:56 CEST	⚠
JDS	UZLeuven	Early Intervention	18 Apr 2016 21:32 CEST	
KLD	UZLeuven	Late Intervention	18 Apr 2016 22:15 CEST	
JDP	UZLeuven	Late Intervention	18 Apr 2016 22:46 CEST	
HP	UZLeuven			
KV	UZLeuven	Late Intervention	21 Apr 2016 14:49 CEST	
IC	UZLeuven	Early Intervention	21 Apr 2016 16:42 CEST	⚠
LL	UZLeuven			
Like	UZLeuven			
LEL	UZLeuven			

Showing 1 to 10 of 10 entries

Subject details

Subject ID

LEL

Site

1: UZLeuven, Belgium

Date entered study

21 Apr 2016

Queries

[Create a new query](#)

CRF

Study entry

Due: 21 Apr 2016 [Mark as data missing](#)

Study entry

Add [View](#) Edit

General information

Add [View](#) Edit

Randomisation

Due: 21 Apr 2016 [Mark as data missing](#)

Randomisation form

[Add](#) [View](#) [Edit](#)

Demographic details

Due: 2 Jun 2016 [Mark as data missing](#)

Demographic details

[Add](#) [View](#) Edit

Intervention

Due: 2 Jun 2016 [Mark as data missing](#)

Operative details

[Add](#) [View](#) Edit

Specify GA and fill out inclusion/exclusion criteria

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TRAPIST | Add Randomisation form | Subject LEL



Subject ID LEL | Date entered study: 21 Apr 2016 | 1: UZLeuven, Belgium

[Return to subject](#)

Randomisation form

Completing this form will randomise the subject.

Randomisation

Gestational age (GA) at inclusion *

- ☐ 11 weeks and 6 days - 12 weeks and 6 days
☒ 13 weeks - 13 weeks and 6 days

Inclusion criteria

All answers must be YES

Does the patient expect a MCDA twin pregnancy complicated by TRAP? *

- ☒ Yes
☐ No

Is the GA between 11.6 weeks and 13.6 weeks? (help) *

- ☒ Yes
☐ No

Can the acardiac twin be accessed safely for early intrafetal ablation? (help) *

- ☒ Yes
☐ No

Does the pump twin appear anatomically normal? *

- ☒ Yes
☐ No

Is the patient 18 years or more and is she able to consent? *

- ☒ Yes
☐ No

Did the patient provide written informed consent to participate in this RCT? *

- ☒ Yes
☐ No

Click randomise

FW: Confidential: new account details - lewiliesbeth@gmail.com - Gmail	TRAPIST Add Randomisation form Subject LEL	+
<div><div><input type="radio"/> No</div><div>Is the GA between 11.6 weeks and 13.6 weeks? <small>(help)</small> *</div><div><input checked="" type="radio"/> Yes</div><div><input type="radio"/> No</div><div>Can the acardiac twin be accessed safely for early intrafetal ablation? <small>(help)</small> *</div><div><input checked="" type="radio"/> Yes</div><div><input type="radio"/> No</div><div>Does the pump twin appear anatomically normal? *</div><div><input checked="" type="radio"/> Yes</div><div><input type="radio"/> No</div><div>Is the patient 18 years or more and is she able to consent? *</div><div><input checked="" type="radio"/> Yes</div><div><input type="radio"/> No</div><div>Did the patient provide written informed consent to participate in this RCT? *</div><div><input checked="" type="radio"/> Yes</div><div><input type="radio"/> No</div></div>		
<div><div>Exclusion criteria</div><div>All answers must be NO</div><div>Is there a contraindication for an intrauterine intervention? <small>(help)</small> *</div><div><input type="radio"/> Yes</div><div><input checked="" type="radio"/> No</div><div>Is there a spontaneous arrest of the reversed flow? *</div><div><input type="radio"/> Yes</div><div><input checked="" type="radio"/> No</div></div>		
<div><div>Notes</div><div></div></div>		
<div>Randomise</div>		
<div>* required</div>		

Subject ID LEL | Date entered study: 21 Apr 2016 | 1: UZLeuven, Belgium

Randomisation form

[Review and sign](#)

This form has not yet been saved. Please complete the declaration below to save the form.

Randomisation

Gestational age (GA) at inclusion

13 weeks - 13 weeks and 6 days

Inclusion criteria

All answers must be YES

Does the patient expect a MCDA twin pregnancy complicated by TRAP?

Yes

Is the GA between 11.6 weeks and 13.6 weeks?

Yes

Can the acardiac twin be accessed safely for early intrafetal ablation?

Yes

Does the pump twin appear anatomically normal?

Yes

Is the patient 18 years or more and is she able to consent?

Yes

Did the patient provide written informed consent to participate in this RCT?

Yes

Extra confirmation

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TRAPIST | Randomisation form | Subject LEL



Does the pump twin appear anatomically normal?

Yes

Is the patient 18 years or more and is she able to consent?

Yes

Did the patient provide written informed consent to participate in this RCT?

Yes

Exclusion criteria

All answers must be NO

Is there a contraindication for an intrauterine intervention?

No

Is there a spontaneous arrest of the reversed flow?

No

Notes

-

Investigator's declaration

By entering my password below I declare that the information presented in this form accurately reflects the medical records, including the results of tests and evaluations performed on the dates specified.

Name

Liesbeth Lewi (ID 1994 - Investigator at UZLeuven)

Date

21 Apr 2016

Password

.....



Confirm

[Back](#)

Extra confirmation –group allocation will appear

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TRAPIST | View Randomisation form | Subject LEL

+

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TRAPIST

Add a subject | Subjects | Queries | Overdue forms

Subject ID LEL | Date entered study: 21 Apr 2016 | 1: UZLeuven, Belgium

Return to subject

➕ Create a query

Randomisation form

The subject was successfully randomised.

Randomised to **Early Intervention** at 21 Apr 2016 22:52 CEST

This form was created at 21 Apr 2016 20:52 UTC by Liesbeth Lewi (ID 1994 - Investigator at UZLeuven)

Randomisation

Gestational age (GA) at inclusion
13 weeks - 13 weeks and 6 days

Inclusion criteria

All answers must be YES

Does the patient expect a MCDA twin pregnancy complicated by TRAP?
Yes

Is the GA between 11.6 weeks and 13.6 weeks?
Yes

Can the second twin be assessed as the first twin's twin by TRAP?

- # Fill out demographic form (shortly) after randomisation
- just to be certain not to miss certain variables e.g. on socio-economic status

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TRAPIST | Subjects

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TRAPIST | Add a subject | Subjects | Queries | Overdue forms

Subjects

Search:

Subject ID	Site	Randomisation group	Date randomised	Status
12	UZLeuven	Early Intervention	16 Apr 2016 17:56 CEST	⚠
JDS	UZLeuven	Early Intervention	18 Apr 2016 21:32 CEST	
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HP	UZLeuven			
KV	UZLeuven	Late Intervention	21 Apr 2016 14:49 CEST	
IC	UZLeuven	Early Intervention	21 Apr 2016 16:42 CEST	⚠
LL	UZLeuven			
Like	UZLeuven			
LEL	UZLeuven	Early Intervention	21 Apr 2016 22:52 CEST	

Showing 1 to 10 of 10 entries

Subject details

Subject ID LEL

Site 1: UZLeuven, Belgium

Date entered study 21 Apr 2016

Randomisation group Early Intervention

Date randomised 21 Apr 2016 22:52 CEST

Queries

[Create a new query](#)

CRF

Study entry

Due: 21 Apr 2016 [Mark as data missing](#)

Study entry Add [View](#) Edit

General information Add [View](#) Edit

Randomisation

Due: 21 Apr 2016 [Mark as data missing](#)

Randomisation form Add [View](#) Edit

Demographic details

Due: 2 Jun 2016 [Mark as data missing](#)

Demographic details Add [View](#) Edit

Add Demographic details form

Intervention

Due: 2 Jun 2016 [Mark as data missing](#)

Demographic form

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TRAPIST | Add Demographic details | Subject LEL

+

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Access | Logout

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TRAPIST

Add a subject

Subjects

Queries

Overdue forms

Subject ID LEL | Date entered study: 21 Apr 2016 | 1: UZLeuven, Belgium

[Return to subject](#)

Demographic details

Demographic details

Parity *

Number (up to 2 digits)

Mode of conception *

☐ Spontaneous

☐ Ovulation induction

☒ IVF or ICSI

History of late miscarriage (help) *

☐ Yes

☒ No

History of preterm birth (help) *

☐ Yes

☒ No

Patient's height *

165

cm. Number (up to 3 digits)

Patient's weight (help) *

54

kg. Number to 1 decimal place

Patient's race/ethnicity (help) *

Demographic form

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TRAPIST | View Demographic details | Subject LEL

+

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TRAPIST

Add a subject

Subjects

Queries

Overdue forms

Subject ID LEL | Date entered study: 21 Apr 2016 | 1: UZLeuven, Belgium

Return to subject

+ Create a query

Go back

Demographic details

This form was saved.

This form was created at 21 Apr 2016 20:53 UTC by Liesbeth Lewi (ID 1994 - Investigator at UZLeuven)

Demographic details

Parity
0
[Number \(up to 2 digits\)](#)

Mode of conception
IVF or ICSI

History of late miscarriage
No

History of preterm birth
No

Patient's height
165
[cm. Number \(up to 3 digits\)](#)

Patient's weight
54
[kg. Number to 1 decimal place](#)

Subsequent forms

Bibliographie de base

Due: 2 Jun 2016 [Mark as data missing](#)

Demographic details [Add](#) [View](#) [Edit](#)

Intervention

Due: 2 Jun 2016 [Mark as data missing](#)

Operative details [Add](#) [View](#) [Edit](#)

Postoperative period

Add Operative details form

Due: 16 Jun 2016 [Mark as data missing](#)

Postoperative complications [Add](#) [View](#) [Edit](#)

Pregnancy and delivery

Due: 17 Nov 2016 [Mark as data missing](#)

Pregnancy and delivery		Add	View	Edit
------------------------	--	---------------------	----------------------	----------------------

Neonatal outcome

Due: 15 Dec 2016 [Mark as data missing](#)

Neonatal details [Add](#) [View](#) [Edit](#)

Long term follow-up

Due: 15 Nov 2018 [Mark as data missing](#)

Long term infant outcome [Add](#) [View](#) [Edit](#)

Study completion form

Due: 27 Dec 2018 [Mark as data missing](#)

Study completion [Add](#) [View](#) [Edit](#)

Withdrawal from follow-up

Due: At any time [Mark as data missing](#)

Withdrawal [Add](#) [View](#) [Edit](#)

Subsequent forms

Bibliographie de base

Due: 2 Jun 2016 [Mark as data missing](#)

Demographic details [Add](#) [View](#) [Edit](#)

Intervention

Due: 2 Jun 2016 [Mark as data missing](#)

Operative details [Add](#) [View](#) [Edit](#)

Postoperative period

Due: 16 Jun 2016 [Mark as data missing](#)

Postoperative complications [Add](#) [View](#) [Edit](#)

Pregnancy and delivery

Due: 17 Nov 2016 [Mark as data missing](#)

Pregnancy and delivery		Add	View	Edit
------------------------	--	---------------------	----------------------	----------------------

Neonatal outcome

Due: 15 Dec 2016 [Mark as data missing](#)

Neonatal details [Add](#) [View](#) [Edit](#)

Long term follow-up

Due: 15 Nov 2018 [Mark as data missing](#)

Long term infant outcome [Add](#) [View](#) [Edit](#)

Study completion form

Due: 27 Dec 2018 [Mark as data missing](#)

Study completion [Add](#) [View](#) [Edit](#)

Withdrawal from follow-up

Due: At any time [Mark as data missing](#)

Withdrawal [Add](#) [View](#) [Edit](#)

Add Postoperative complications form

Postoperative complications within 2 weeks

These are also (S)AE and should be communicated to steering committee within 24 hours

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TRAPIST | Add Postoperative complications | Subject LEL



Postoperative complications

within the first 2 weeks after the intervention

Maternal postoperative complications

If the answer is YES to any of the following items, report within 24 hours as a (potential) serious adverse event (SAE) - SAE forms are available on the study website www.monochorionictwins.org

Need for transfusion for postoperative hemorrhage *

- ☐ Yes
☐ No

Placental abruption *

- ☐ Yes
☐ No

Sepsis *

- ☐ Yes
☐ No

Bowel perforation *

- ☐ Yes
☐ No

Admission of the patient to ICU *

- ☐ Yes
☐ No

If admission to ICU, please specify circumstances

Death of the patient *

- ☐ Yes
☐ No

If maternal death, please specify circumstances

Notes

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TRAPIST

Add a subject

Subjects

Queries

Overdue forms

Overdue forms

[View a summary](#)

Detail by subject




























Key  Form completed  Form overdue  Not due yet  Form missing  Subject withdrew  Form is not applicable

Visits **A:** Study entry **B:** Randomisation **C:** Demographic details **D:** Intervention **E:** Postoperative period **F:** Pregnancy and delivery **G:** Neonatal outcome **H:** Long term follow-up **I:** Study completion form

[Download as CSV](#)

Click an entry to display the form and visit name.

Search:

Subject ▾	Site	↕	A	B	C	D	E	F	G	H	I
12	UZLeuven										
HP	UZLeuven										
IC	UZLeuven										
JDP	UZLeuven										
JDS	UZLeuven										
KLD	UZLeuven										
KV	UZLeuven										
LEL	UZLeuven										
Like	UZLeuven										
LL	UZLeuven										

Showing 1 to 10 of 10 entries