To whom it may concern,

The trial: "Een verbetering van de analgesie na episiotomie door epidurale toediening van neostigmine en clonidine." protcol MVDV 10/07 – EudraCT 2007-005512-12" was prematurely ended on 31 Dec 2008 due to organizational reasons.

Yours sincerely,

Prof. Dr. M. Van de Velde

Declaration of the End of Trial Form (cf. Section 4.2.1 of the *Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial*[1])

NOTIFICATION OF THE END OF A CLINICAL TRIAL OF A MEDICINE FOR HUMAN USE TO THE COMPETENT AUTHORITY AND THE ETHICS COMMITTEE

For official use

Date of receipt :	Competent authority registration number : Ethics committee registration number:

To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE :

B TRIAL IDENTIFICATION

B.1 EudraCT number :	**2007-005512-12**
B.2 Sponsor's protocol code number:	**MVDV 10/07**
B.3 Full title of the trial:	***Een verbetering van de analgesie na episiotomie door epidurale toediening van neostigmine en clonidine.***

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1	**DECLARATION FOR THE COMPETENT AUTHORITY**	X
C.1.1	Sponsor	X
C.1.2	Legal representative of the sponsor	☐
C.1.3	Person or organisation authorised by the sponsor to make the application.	☐
C.1.4	**Complete below**:	
C.1.4.1	Organisation :University Hospitals Leuven	
C.1.4.2	Name of person to contact : Marc Van de Velde	
C.1.4.3	Address :Herestraat 49, B- 3000 Leuven	
C.1.4.4	Telephone number : +32 16 34 42 70	
C.1.4.5	Fax number :	
C.1.4.6	E-mail: marc.vandevelde@uzleuven.be	

C.2	**DECLARATION FOR THE ETHICS COMMITTEE**	X
C.2.1	Sponsor	☐
C.2.2	Legal representative of the sponsor	☐
C.2.3	Person or organisation authorised by the sponsor to make the application.	☐
C.2.4	Investigator in charge of the application if applicable[2]:	
	• Co-ordinating investigator (for multicentre trial):	☐
	• Principal investigator (for single centre trial):	X
C.2.5	**Complete below** :	
C.2.5.1	Organisation: University Hospitals Leuven	
C.2.5.2	Name : Marc Van de Velde	
C.2.5.3	Address : Herestraat 49,B- 3000 Leuven	
C.2.5.4	Telephone number : +32 16 34 42 70	
C.2.5.5	Fax number :	
C.2.5.6	E-mail : marc.vandevelde@uzleuven.be	

1 OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.

2 According to national legislation.

D END OF TRIAL

D.1 Date of the end of the trial in this Member State ?[3]	yes X no ☐
D.1.1. (YYYY/MM/DD):2008-12-31	

D.2	**Date of the end of the complete trial in all countries concerned by the trial**?[3]	yes X no ☐
D.2.1	(YYYY/MM/DD): 2008-12-31	

D.3	**Is it an early termination?**[4]	Yes X no ☐
D.3.1	If yes, give date (YYYY/MM/DD): 2008-12-31	
D.3.2	Briefly describe in an annex (free text):	
D.3.2.1	The justification for early termination of the trial; organizational reasons	
D.3.2.2	Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management; none	
D.3.2.3	The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product. none	

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

E.1 I hereby confirm that/confirm on behalf of the sponsor that (delete which is not applicable):

- The above information given on this declaration is correct; and
- That the clinical trial summary report will be submitted within the applicable deadlines in accordance with the applicable guidance by the Commission.[5]

E.2	**APPLICANT TO THE COMPETENT AUTHORITY** (as stated in C.1)	☒
E.2.1	Date : 27 06 2022	
E.2.2	Signature :	
E.2.3	Print name: Marc Van de Velde	

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:**	☒
E.3.1	Date : 27 06 2022	
E.3.2	Signature :	
E.3.3	Print name: Marc Van de Velde	

---

[3] In case of a multi-country trial, if the national and global end of trial dates are different in a given Member State, the sponsor shall submit this form two times :

1) At the end of the trial in the individual Member State, section D1.1. shall be completed and submitted to the respective National Competent Authority.

2) At the global end of the trial, the sponsor shall complete section D.2.1. with the global trial end date and the completed form shall be submitted to all participating Member States in order to allow the sponsor to prepare the trial result summary within the 12-months (or 6-months in case of paediatric trials) timeframe.

If the national and global end dates coincide in a concerned Member State, the form shall be submitted only once to the National Competent Authority of this Member State with both sections D1.1. and D2.1 complete.

[4] Cf. Section 4.2. of the detailed guidance CT-1.

[5] Section 4.3. of the detailed guidance CT-1.

To whom it may concern,

The study: "*The influence of prophylactic ephedrine on arterial hypotension and fetal dysrhythmia after spinal-epidural anesthesia during labour. A randomized, prospective, dubbel-blind study. EudraCT 2006-002456-15" never started.*

Yours sincerely,

Prof. Dr. M. Van de Velde

To whom it may concern,

The study:" ***Een gecombineerde spinale epidurale anesthesie (CSE) bij arbeid: nood aan een fluid load (colloïden)*** *Protocol ANE 08/06– EudraCT 2006-004629-28"* never started.

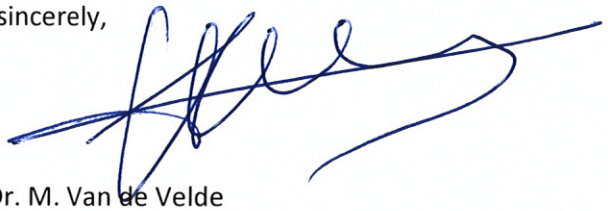
Yours sincerely,

Prof. Dr. M. Van de Velde

To whom it may concern,

The study:" ***Vergelijkende studie tussen PCEA en TAP-block als postoperatieve pijnstilling bij sectio patiënten. Protocol MVDV 11/09 – EudraCT 2009-017326-39***" prematurely ended on 31 OCT 2010 due to organizational reasons.

Yours sincerely,



Prof. Dr. M. Van de Velde

Declaration of the End of Trial Form (cf. Section 4.2.1 of the *Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial*[1])

NOTIFICATION OF THE END OF A CLINICAL TRIAL OF A MEDICINE FOR HUMAN USE TO THE COMPETENT AUTHORITY AND THE ETHICS COMMITTEE

For official use

Date of receipt :	Competent authority registration number : Ethics committee registration number:

To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE :

B TRIAL IDENTIFICATION

B.1 EudraCT number :	**2009-017326-39**
B.2 Sponsor's protocol code number:	**MVDV 11/09**
B.3 Full title of the trial :	***Vergelijkende studie tussen PCEA en TAP-block als postoperatieve pijnstilling bij sectio-patiënten.***

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1	**DECLARATION FOR THE COMPETENT AUTHORITY**	X
C.1.1	Sponsor	X
C.1.2	Legal representative of the sponsor	☐
C.1.3	Person or organisation authorised by the sponsor to make the application.	☐
C.1.4	**Complete below**:	
C.1.4.1	Organisation :University Hospitals Leuven	
C.1.4.2	Name of person to contact : Marc Van de Velde	
C.1.4.3	Address :Herestraat 49, B- 3000 Leuven	
C.1.4.4	Telephone number : +32 16 34 42 70	
C.1.4.5	Fax number :	
C.1.4.6	E-mail: marc.vandevelde@uzleuven.be	

C.2	**DECLARATION FOR THE ETHICS COMMITTEE**	X
C.2.1	Sponsor	☐
C.2.2	Legal representative of the sponsor	☐
C.2.3	Person or organisation authorised by the sponsor to make the application.	☐
C.2.4	Investigator in charge of the application if applicable[2]:	
	• Co-ordinating investigator (for multicentre trial):	☐
	• Principal investigator (for single centre trial):	X
C.2.5	**Complete below** :	
C.2.5.1	Organisation: University Hospitals Leuven	
C.2.5.2	Name : Marc Van de Velde	
C.2.5.3	Address : Herestraat 49,B- 3000 Leuven	
C.2.5.4	Telephone number : +32 16 34 42 70	
C.2.5.5	Fax number :	
C.2.5.6	E-mail : marc.vandevelde@uzleuven.be	

1 OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.

2 According to national legislation.

D END OF TRIAL

D.1 Date of the end of the trial in this Member State ?[3]	yes X no ☐
D.1.1. (YYYY/MM/DD):2010-10-31	

D.2 Date of the end of the complete trial in all countries concerned by the trial?[3]	yes X no ☐
D.2.1 (YYYY/MM/DD): 2010-10-31	

D.3 Is it an early termination?[4]	yes X no ☐
D.3.1 If yes, give date (YYYY/MM/DD): 2010-10-31	
D.3.2 Briefly describe in an annex (free text):	
D.3.2.1 The justification for early termination of the trial; organizational reasons	
D.3.2.2 Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management; none	
D.3.2.3 The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product. none	

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

E.1 I hereby confirm that/confirm on behalf of the sponsor that (delete which is not applicable):

- The above information given on this declaration is correct; and
- That the clinical trial summary report will be submitted within the applicable deadlines in accordance with the applicable guidance by the Commission.[5]

E.2 APPLICANT TO THE COMPETENT AUTHORITY (as stated in C.1)	☒
E.2.1 Date : 27 06 2022	
E.2.2 Signature :	
E.2.3 Print name: Marc Van de Velde	

E.3 APPLICANT TO THE ETHICS COMMITTEE (as stated in C.2) :	☒
E.3.1 Date : 27 06 2022	
E.3.2 Signature :	
E.3.3 Print name: Marc Van de Velde	

---

[3] In case of a multi-country trial, if the national and global end of trial dates are different in a given Member State, the sponsor shall submit this form two times :

1) At the end of the trial in the individual Member State, section D1.1. shall be completed and submitted to the respective National Competent Authority.

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If the national and global end dates coincide in a concerned Member State, the form shall be submitted only once to the National Competent Authority of this Member State with both sections D1.1. and D2.1 complete.

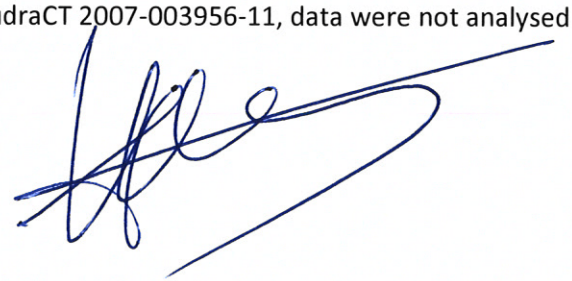
[4] Cf. Section 4.2. of the detailed guidance CT-1.

[5] Section 4.3. of the detailed guidance CT-1.

To whom it may Concern,

The study: "*Low dose of ephedrine versus phenylephrine in the prevention of arterial hypotension after low dosed CSE for elective C-section : is there a difference in umbilical blood gas values?*"- Protocol MVDV 07/2007– EudraCT 2007-003956-11, data were not analysed.

Yours sincerely,



Prof. Dr. M. Van de Velde

Declaration of the End of Trial Form (cf. Section 4.2.1 of the *Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial*[1])

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For official use

Date of receipt :	Competent authority registration number : Ethics committee registration number:

To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE :

B TRIAL IDENTIFICATION

B.1 EudraCT number :	**2007-03956-11**
B.2 Sponsor's protocol code number:	**MVDV 07/2007**
B.3 Full title of the trial :	***Low dose of ephedrine versus phenylephrine in the prevention of arterial hypotension after low dosed CSE for elective_C-section: is there a difference in umbilical blood gas values?***

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1	**DECLARATION FOR THE COMPETENT AUTHORITY**	X
C.1.1	Sponsor	X
C.1.2	Legal representative of the sponsor	☐
C.1.3	Person or organisation authorised by the sponsor to make the application.	☐
C.1.4	**Complete below**:	
C.1.4.1	Organisation :University Hospitals Leuven	
C.1.4.2	Name of person to contact : Marc Van de Velde	
C.1.4.3	Address :Herestraat 49, B- 3000 Leuven	
C.1.4.4	Telephone number : +32 16 34 42 70	
C.1.4.5	Fax number :	
C.1.4.6	E-mail: marc.vandevelde@uzleuven.be	

C.2	**DECLARATION FOR THE ETHICS COMMITTEE**	X
C.2.1	Sponsor	☐
C.2.2	Legal representative of the sponsor	☐
C.2.3	Person or organisation authorised by the sponsor to make the application.	☐
C.2.4	Investigator in charge of the application if applicable[2]:	
	• Co-ordinating investigator (for multicentre trial):	☐
	• Principal investigator (for single centre trial):	X
C.2.5	**Complete below** :	
C.2.5.1	Organisation: University Hospitals Leuven	
C.2.5.2	Name : Marc Van de Velde	
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2 According to national legislation.

D END OF TRIAL

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D.1.1. (YYYY/MM/DD):2008-12-31	

D.2 Date of the end of the complete trial in all countries concerned by the trial?[3]	yes X no ☐
D.2.1 (YYYY/MM/DD): 2008-12-31	

D.3 Is it an early termination?[4]	Yes ☐ no X
D.3.1 If yes, give date (YYYY/MM/DD):	
D.3.2 Briefly describe in an annex (free text):	
D.3.2.1 The justification for early termination of the trial;	
D.3.2.2 Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management; none	
D.3.2.3 The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product. none	

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

E.1 I hereby confirm that/confirm on behalf of the sponsor that (delete which is not applicable):

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- That the clinical trial summary report will be submitted within the applicable deadlines in accordance with the applicable guidance by the Commission.[5]

E.2 APPLICANT TO THE COMPETENT AUTHORITY (as stated ~~in C~~.1)	☒
E.2.1 Date : 27 06 2022	
E.2.2 Signature :	
E.2.3 Print name: Marc Van de Velde	

E.3 APPLICANT TO THE ETHICS COMMITTEE (as stated ~~in C~~.2) **:**	☒
E.3.1 Date : 27 06 2022	
E.3.2 Signature :	
E.3.3 Print name: Marc Van de Velde	

---

[3] In case of a multi-country trial, if the national and global end of trial dates are different in a given Member State, the sponsor shall submit this form two times :

1) At the <u>end of the trial in the individual Member State</u>, section D1.1. shall be completed and submitted to the respective National Competent Authority.

2) At the <u>global end of the trial</u>, the sponsor shall complete section D.2.1. with the global trial end date and the completed form shall be submitted <u>to all participating Member States</u> in order to allow the sponsor to prepare the trial result summary within the 12-months (or 6-months in case of paediatric trials) timeframe.

If the national and global end dates coincide in a concerned Member State, the form shall be submitted only once to the National Competent Authority of this Member State with both sections D1.1. and D2.1 complete.

[4] Cf. Section 4.2. of the detailed guidance CT-1.

[5] Section 4.3. of the detailed guidance CT-1.