Remifentanil patient controlled **A**nalgesia **V**ersus **E**pidural analgesia in **L**abor.

A randomized multicenter equivalence trial.

Liv Freeman

Namens de RAVEL projectgroep

GGG congres 16-10-'15

Disclosure

- Belangenverstrengeling: geen
- Subsidie: ZonMw.

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Studies in Obstetrics, Fertility & Gynaecology

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Pijnstilling durante partu

Richtlijn medicamenteuze pijnbestrijding tijdens de bevalling:

- Epidurale pijnstilling meest effectief, aanbevolen als eerste keus.
- Remifentanil alleen in onderzoeksverband.

Echter:

- Epidurale pijnstilling niet overal 24/7 beschikbaar.
- Remifentanil wordt in >30% van de ziekenhuizen gebruikt.

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Epidurale analgesie

- Nederland 15% (2010), andere westerse landen 40-80%.
- Beste pijnstilling, grootste reductie pijn-intensiteits score.
- Soms niet mogelijk door contra-indicatie.

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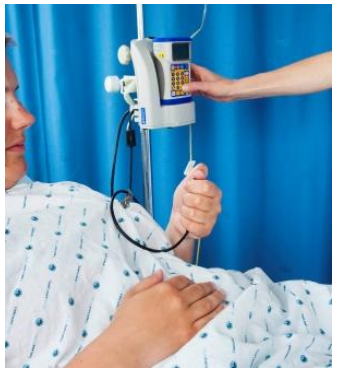
Remifentanil PCA

- Synthetisch opioid.
- Geschikt voor toediening middels PCA:
  - Snel optredend effect
- Passeert de placenta
  - snel gemetaboliseerd
  - snel geredistribueerd



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Hinova A, Fernando R. Systemic remifentanil for labor analgesia. Anesth Analg. 2009 Dec;109(6):1925-9.

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Pijnstilling durante partu

- Epidurale analgesie geeft superieure pijnstilling (pijn scores) ten opzichte van remifentanil PCA.
- Pijn appreciatie lijkt vergelijkbaar te zijn.
- Potentieel lagere kosten bij gebruik van remifentanil PCA.

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Studies in Obstetrics, Fertility & Gynaecology

Volmanen et al. Acta Anaesthesiol Scand 2008.
Douma et al. Int J Obst Anesth 2011.

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Hypothese

Remifentanil PCA is equivalent aan epidurale analgesie wat betreft pijn appreciatie.

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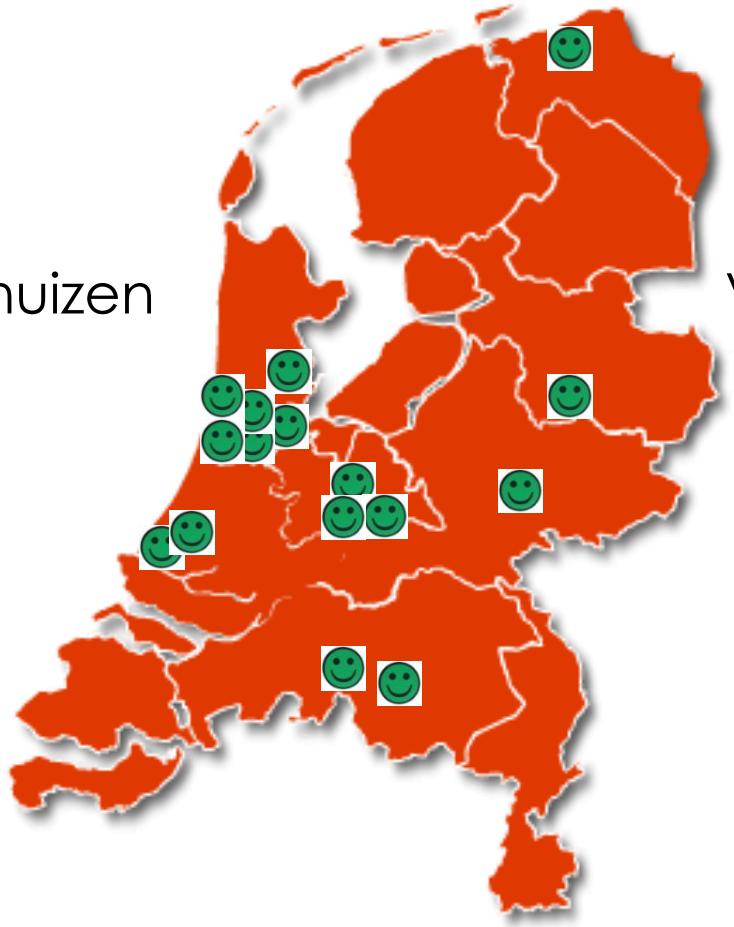
Design

15 ziekenhuizen



Verloskundig Consortium

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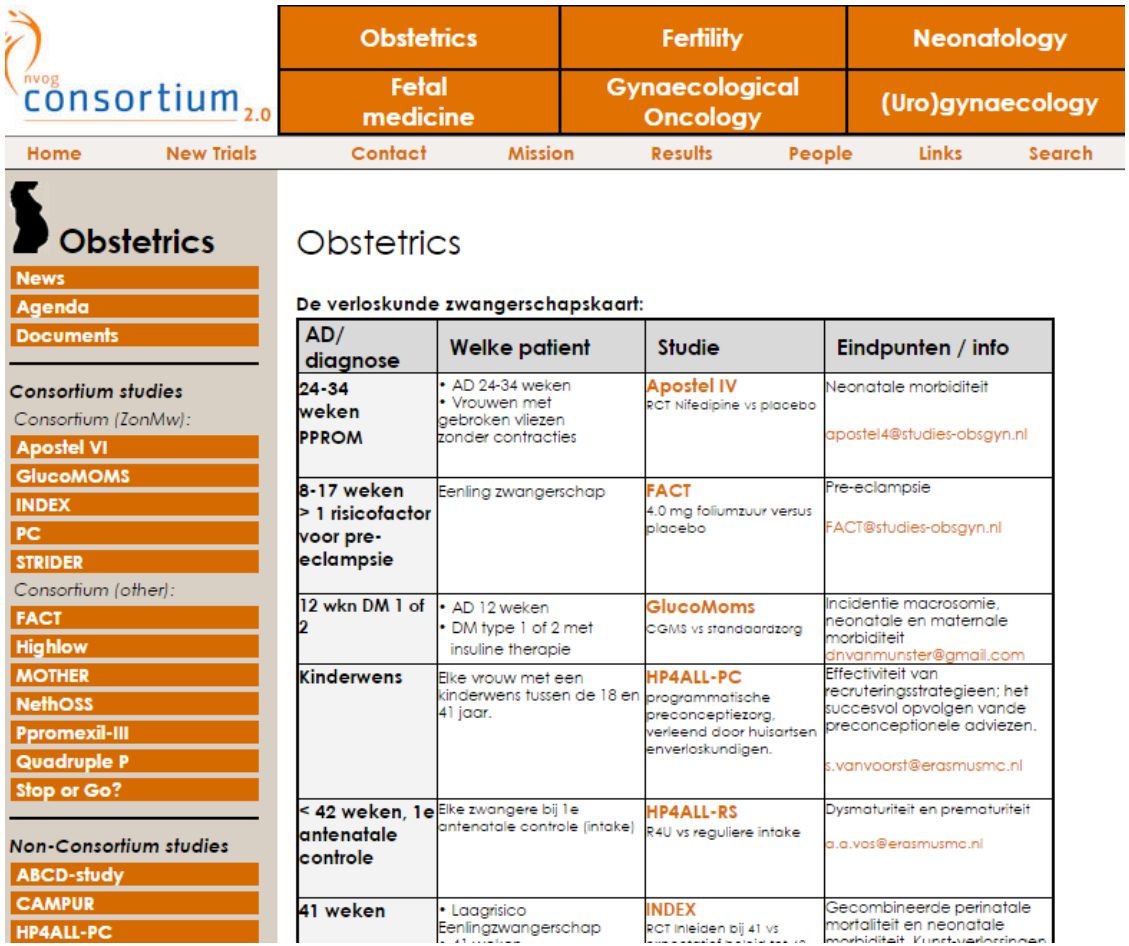
NVOG consortium 2.0



nvog consortium 2.0

Obstetrics | Fertility | Neonatology
Fetal medicine | Gynaecological Oncology | (Uro)gynaecology

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Obstetrics

- News
- Agenda
- Documents

Consortium studies

Consortium (ZonMw):

- Apostel VI
- GlucoMOMS
- INDEX
- PC
- STRIDER

Consortium (other):

- FACT
- Highlow
- MOTHER
- NethOSS
- Ppromexil-III
- Quadruple P
- Stop or Go?

Non-Consortium studies

- ABCD-study
- CAMPUR
- HP4ALL-PC

Obstetrics

De verloskunde zwangerschapskaart:

AD/ diagnose	Welke patient	Studie	Eindpunten / info
24-34 weken PPROM	• AD 24-34 weken • Vrouwen met gebroken vliezen zonder contracties	Apostel IV RCT Nifedipine vs placebo	Neonatale morbiditeit apostel4@studies-obsgyn.nl
8-17 weken > 1 risicofactor voor pre-eclampsie	Eenling zwangerschap	FACT 4.0 mg foliumzuur versus placebo	Pre-eclampsie FACT@studies-obsgyn.nl
12 wkn DM 1 of 2	• AD 12 weken • DM type 1 of 2 met insuline therapie	GlucoMoms CGMS vs standaardzorg	Incidentie macrosomie, neonatale en maternale morbiditeit dnvanmunster@gmail.com
Kinderwens	Elke vrouw met een kinderwens tussen de 18 en 41 jaar.	HP4ALL-PC programmatische preconceptiezorg, verleend door huisartsen enverloskundigen.	Effectiviteit van recruteringsstrategieen; het succesvol opvolgen vande preconceptionele adviezen. s.vanvoorst@erasmusmc.nl
< 42 weken, 1e antenatale controle	Elke zwangere bij 1e antenatale controle (intake)	HP4ALL-RS R4U vs reguliere intake	Dysmaturiteit en prematuriteit a.a.vos@erasmusmc.nl
41 weken	• Laagrisico Eenlingzwangerschap	INDEX RCT Inleiden bij 41 vs	Gecombineerde perinatale mortaliteit en neonatale

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Primaire uitkomstmaat

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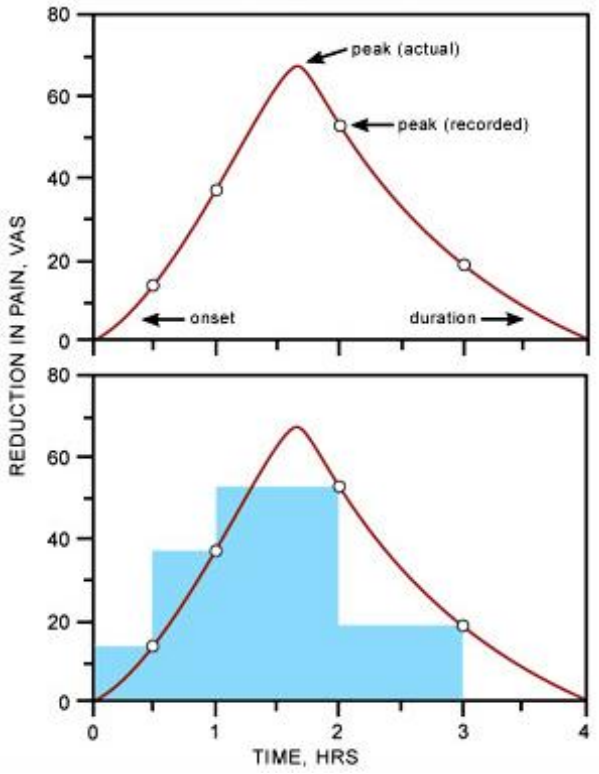
Area under the curve

- De AUC geeft het cumulatief effect, of in dit geval de cumulatieve pijn appreciatie, in een bepaalde periode weer.

- Totale duur van de partus
- Voor de duur van pijnbestrijding

- Hoe hoger de AUC hoe hoger de pijn appreciatie.



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Primaire uitkomstmaat

Daarnaast:

- Kosteneffectiviteit

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Secundaire uitkomsten

- Pijn score
  - Gemeten op een VAS schaal
  - Uitgedrukt als area under the curve
- Tevredenheidsscore
  - "rapportcijfer" voor de pijn post partum
- Maternale bijwerkingen
- Modus partus
- Maternale mortaliteit en morbiditeit
- Neonatale mortaliteit en morbiditeit

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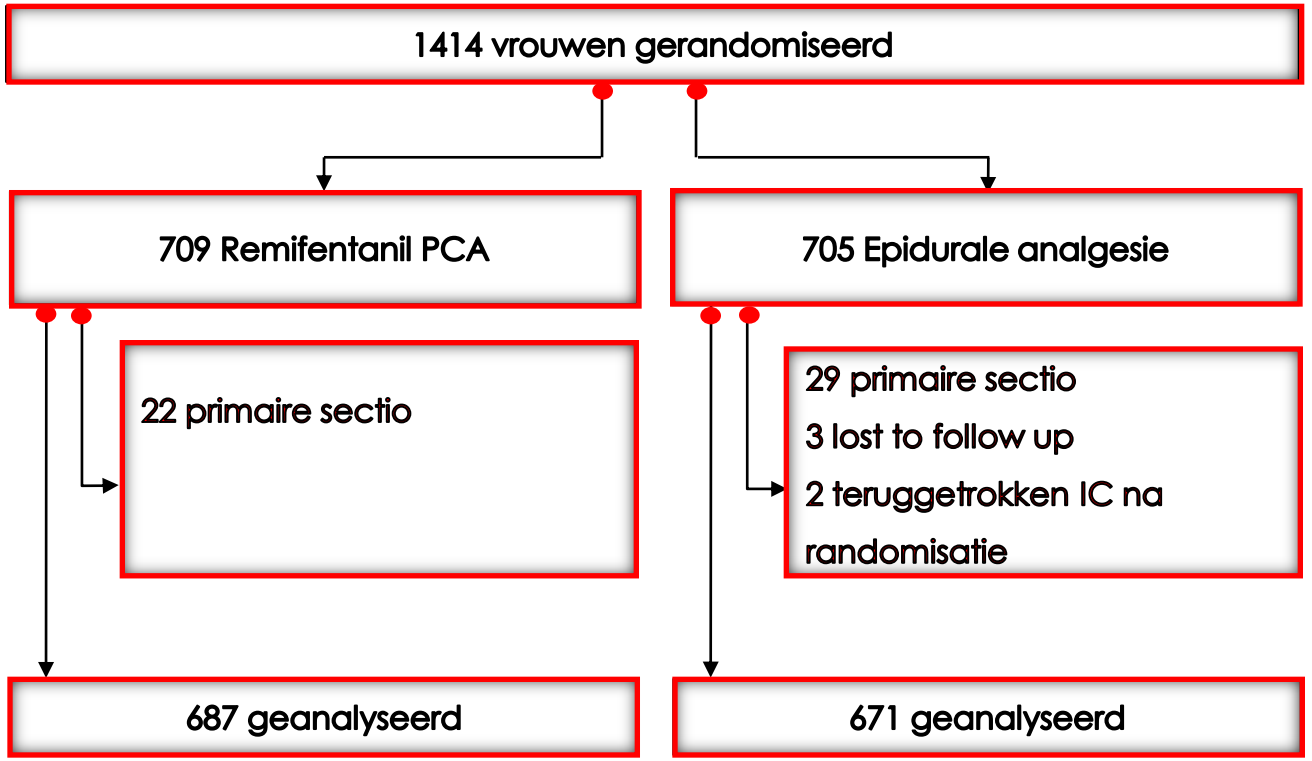
Sample size en analyse

- Klinisch relevant verschil: 10%
- 1136 patienten (α 0.05, β 0.10)
- 50% pijnstilling, 10/30% crossover/non-compliance
- Verhoogd naar 1400

- Intention to treat analyse, herhaald voor vrouwen die pijnstilling kregen.
- Meervoudige imputatie om te corrigeren voor missende data.

Studie populatie



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Resultaten: baseline

	Remifentanil PCA N=687	Epidural analgesia N=671
GA at randomisation (weeks; median [IQR])	37.8 [35.5-39.2]	37.1 [35.3-39.0]
Maternal age (years; means [SD])	31.5 [5.1]	31.7 [4.8]
Ethnic origin*		
Caucasian	579 (88.0%)	561 (89.3%)
Non-caucasian	79 (12.0%)	67 (10.7%)
Education		
≥higher professional	281 (52.2%)	296 (55.4%)
Body mass index (median [IQR])	23.7 [21.5-26.9]†	23.8 [21.4-27.6] ‡
ASA classification		
ASA 1	491 (71.5%)	461 (68.7%)
ASA 2	196 (28.5%)	210 (31.3%)
Parity		
0	323 (47%)	329 (49%)
≥1	364 (53%)	342 (51%)
Multiple pregnancy	24 (3.5%)	30 (4.5%)

Studie populatie

709 Remifentanil PCA

240 (35%) geen pijnstilling

402 (59%) RPCA
53 (13%) conversie naar EA

41 (6%) EA

4 (<1%) andere opioiden

705 Epidurale analgesie

324 (48%) geen pijnstilling

296 (44%) EA
3 (1%) conversie naar RPCA

33 (5%) RPCA
2 conversie naar EA

18 (3%) andere opioiden

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Pijn appreciatie

	RPCA	EA	P value	Difference (95% CI)
During active labor				
AUC pain appreciation (mean)	30.5	34.2	0.07	3.7 (-0.3-7.6)
N= 687/671				
After start pain relief				
AUC pain appreciation (mean)	25.7	36.8	<0.001	11.1 (7.5-14.7)
N= 447/347				

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Resultaten: partus

	Remifentanil PCA N=687	Epidural analgesia N=671	RR (95% CI)	p value
Request pain relief	447 (65.1%)	347 (51.7%)	1.32 (1.18-1.48)	<0.001
Time from request to start analgesia (min; median [IQR])	28 [15-45]	55 [32-80]		<0.001
Gestational age at delivery (weeks; median [IQR])	39.7 [38.3-40.7]	39.7 [38.3-40.7]		0.37
Onset of labor				
Spontaneous	282 (41%)	281 (41.9%)	0.98 (0.88-1.09)	0.76
Induction	405 (59%)	390 (58.1%)	1.02 (0.91-1.32)	0.76
Dilatation at request pain relief (cm; median [IQR])	4 [3-5]	4 [3-5]		0.94

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Resultaten: partus

	Remifentanil PCA N=687	Epidural analgesia N=671	RR (95% CI)	p value
Duration of analgesia (min; median [IQR])	236 [128-376]	309 [181-454]		<0.001
Duration second stage of labor (min; median [IQR])	20 [10-46]	24 [10-53]		0.09
Fetal condition at start pain relief (CTG) n=794				
Optimal	400 (90.1%)	315 (90.8%)	0.96 (0.80-1.17)	0.71
Augmentation with oxytocin	394 (57.5%)	391 (58.4%)	0.97 (0.87-1.08)	0.61
Mode of delivery				
Spontaneous	518 (75.4%)	501 (74.7%)	1.02 (0.90-1.15)	0.75
Vaginal instrumental	63 (9.2%)	70 (10.4%)	0.93 (0.77-1.13)	0.45
Ceserean section	106 (15.4%)	100 (14.9%)	1.01 (0.88-1.17)	0.87

Maternale and neonatale uitkomst

	Remifentanil PCA N=687	Epidural analgesia N=671	RR (95% CI)	p value
Postpartum hemorrhage (≥1000 ml)	52 (7.7%)	66 (10.1%)	0.86 (0.69-1.06)	0.13
Apgar score <7 5 min	11 (1.6%)	15 (2.2%)	0.84 (0.53-1.31)	0.40
pHa <7.10	22 (4.5%)	28 (5.9%)	0.86 (0.63-1.19)	0.34
Postspinal headache	1 (0.2%)	4 (1.2%)		0.21
Maternal admission	419 (61%)	416 (62%)	0.98 (0.88-1.09)	0.70
Length of admission (days; median [IQR])	1 [1-3]	1 [1-3]		0.24
Neonatal admission	390 (56.8%)	385 (57.4)	0.99 (0.89-1.10)	0.82
Length of admission neonate 1 (days; median [IQR])	1 [1-3]	1 [1-3]		0.13
Length of admission neonate 2 (days; median [IQR])	3 (2.00-5.75)	4.5 (2.25-13.25)		0.42

Kostenanalyse

- Geen equivalentie dus geen kosteneffectiviteit.
- Kosten vanaf start partus tot 10 dagen postpartum.
- Gezondheidszorgperspectief
- Geconverteerd naar 2014 euro's
- Gebruik gerapporteerd in CRF en vragenlijst

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Kosten analyse: methoden en bronnen

Informatie van de financiële afdelingen

- Bevalling
- opname

Gestandaardiseerde kostprijzen (Hakkaart et al)

- Verloskundige
- huisarts
- SEH
- bloedproducten

www.medicijnkosten.nl

- Medicatie

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Kosten analyse: methoden en bronnen

Bottom up benadering kosten pijnstilling:

- epiduraal catheter en instrumentarium
- kosten medicatie
- kosten personeel

Niet: kosten monitoring

Kostenanalyse

	Remifentanil PCA mean	Epidural analgesia mean
Analgesia	**34,44**	**40,42**
Delivery	952,79	957,77
Medication during labour		
antihypertensives	0,03	0,03
oxytocin	0,37	0,37
antibiotics	0,37	0,54
Fetal scalp sampling	10,56	10,71
Medication third stage	6,53	7,15
Operative removal (incomplete) placenta	31,83	38,64
Repair of perineal tear in theatre	60	59,86
Bloodtransfusion	11,04	19,17
Total third stage		
Total delivery	**1108,21**	**1135,23**
Maternal admission	**559,47**	**615,52**
Neonatal admission	**1036,38**	**1225,7**
10 days postpartum		
Midwife	100,11	100,42
General practicioner	29,92	27,36
Obstetrician	8,98	9,91
Pediatrician	12,88	16,77
Emergency department	7,41	6,11
Total postpartum	**159,3**	**160,57**
Total	**2863,36**	**3137,02**

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Kosten: resultaten

Remifentanil PCA	€2863
Epidural analgesie	€3137

Mean difference -€271 (95% CI -€602 to €60).

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Conclusie: pijn appreciatie

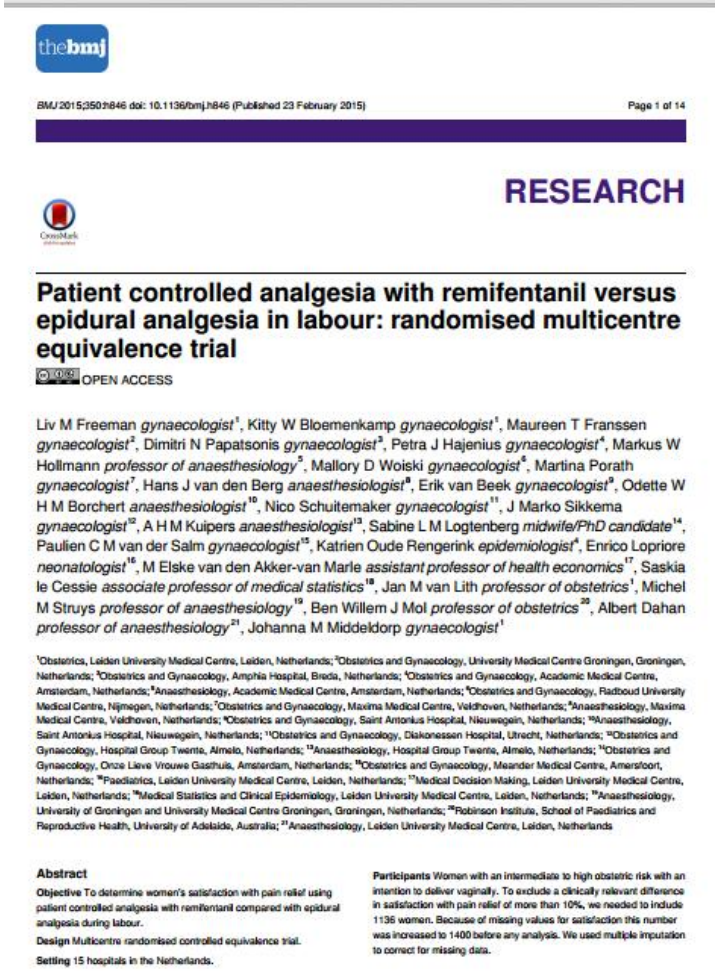
Remifentanil PCA is niet equivalent aan epidurale analgesie.

Pijn appreciatie scores (AUC) van vrouwen, met een verzoek voor pijnstilling, gerandomiseerd voor epidurale analgesie, zijn significant hoger.

Conclusie: kosten

Omdat de kosten niet significant verschillen is er vanuit economisch oogpunt geen behandeling van eerste keus.

Heden: verspreiding



thebmj

BMJ 2015;350:h846 doi: 10.1136/bmj.h846 (Published 23 February 2015)

RESEARCH

Patient controlled analgesia with remifentanil versus epidural analgesia in labour: randomised multicentre equivalence trial

OPEN ACCESS

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Abstract

Objective To determine women's satisfaction with pain relief using patient controlled analgesia with remifentanil compared with epidural analgesia during labour.

Design Multicentre randomised controlled equivalence trial.

Setting 15 hospitals in the Netherlands.

Participants Women with an intermediate to high obstetric risk with an intention to deliver vaginally. To exclude a clinically relevant difference in satisfaction with pain relief of more than 10%, we needed to include 1136 women. Because of missing values for satisfaction this number was increased to 1400 before any analysis. We used multiple imputation to correct for missing data.

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Blik op de toekomst

- Implementatie
  - herziening richtlijn
    - indicatie gebied
    - protocollaire bewaking
  - scholing

- Follow up?

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ZonMw

Maxima Medisch Centrum - Veldhoven

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ZonMW

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Resultaten
subgroep analyse pijnstilling

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AUC pijn appreciatie 0-4 uur

AUC 0-4 uur	RPCA	EA	P value	Difference (95% CI)
Pijn appreciatie score (means [SD])	18.8	27.1	<0.001	8.3 (6.1-10.6)
Pijn score (means [SD])	17.6	11.7	<0.001	5.9 (4.5-7.2]

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Multipara

AUC na starten pijnstilling	RPCA	EA	P value	Difference (95% CI)
Pijn appreciatie (mean) N= 214/142	17.8	27.8	<0.001	10.0 (5.6-14.4)
Pijn (mean) N= 214/142	20.0	16.5	0.05	3.5 (-0.03-7.1)

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Nullipara

AUC na starten pijnstilling	RPCA	EA	P value	Difference (95% CI)
Pijn appreciatie (mean) N= 233/205	32.7	42.4	<0.001	9.7 (4.4-15.1)
Pijn (mean) N= 233/205	33.0	23.6	<0.001	9.4 (5.1-13.6)

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Pijn score

	RPCA	EA	P value	Difference (95% CI)
During active labor Pain score (mean) N= 687/671	30.7	27.2	0.02	3.6 (0.5-6.6)
After start pain relief Pain score (mean) N= 447/347	26.9	20.7	<0.001	6.2 (3.1-9.2)

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Resultaten: overall score itt

	RPCA	EA	P value	Difference (95% CI)
Overall score totaal N= 687/671	6.89 (6-8)	7.15 (7-8)	0.09	-0.26 (-0.56-0.04)

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Resultaten: overall score

	RPCA	EA	P value	Difference (95% CI)
Overall score Tijdens pijnstilling N= 447/347	6.79 [2.14]	7.25 [2.26]	0.02	0.47 (0.08-0.86)

Uitkomsten

Enige verschillen tussen gehele en pijnstillingsgroep:

- Pijnstilling nulli vs multiparae
- Duur uitdrijving

	Remifentanil PCA N=447	Epidural analgesia N=347	p value
Parity			
0	233 (52.1%)	205 (59.1%)	0.05
≥1	214 (47.9%)	142 (40.9%)	
Duration second stage of labor (hour, median [IQR])	0.42 [0.18-0.85]	0.57 [0.25-1.00]	0.01

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Neveneffecten

	Remifentanil PCA N=447	Epidural analgesia N=347	RR (95% CI)	p value
Hypotension <90 systolic nr of patients	29 (6.7%)	38 (11.3%)	0.75 (0.57-1.00)	0.03

Neveneffecten

	Remifentanil PCA N=447	Epidural analgesia N=347	RR (95% CI)	p value
Maximum temperature °C median [IQR] (range)	37.0 [36.6-37.4] 35.0-39.4	37.3 [36.7-37.8] 35.1-40.4		<0.001
Temperature mean [SD]	36.7 [0.54]	37.0 [0.62]		<0.001
Temperature ≥38 °C during labor	**36 (8.8%)**	**57 (18.8%)**	**0.65 (0.50-0.85)**	**<0.001**
Suspected infection treated with antibiotics	16 (3.6%)	23 (6.6%)	0.72 (0.49-1.05)	0.05

Neveneffecten

	Remifentanil PCA N=447	Epidural analgesia N=347	RR (95% CI)	p value
Minimum saturation % median [IQR] (range)	95 [93-97] (50-100)	97 [96-98] (76-100)		<0.001
Saturation mean [SD]	97.4 [1.6]	98.2 [1.4]		<0.001
Saturation <92% (nr of patients)	**75 (18.9%)**	**16 (5.8%)**	**1.5 (1.3-1.7)**	**<0.001**

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Maternal outcome

	Remifentanil PCA N=447	Epidural analgesia N=347	RR (95% CI)	p value
Time from request to start analgesia (hour, median [IQR])	0.47 [0.25-0.75]	0.92 [0.53-1.33]		<0.001
Gestational age at delivery (weeks; median [IQR])	39.9 [38.6-40.9]	39.6 [38.3-40.9]		0.18
Onset of labor				
Spontaneous	150 (33.6%)	121 (34.9%)	0.98 (0.86-1.11)	0.70
Induced	297 (66.4%)	226 (65.1%)	1.03 (0.90-1.17)	0.70
Dilatation at request pain relief (cm; median [IQR])	4 [3-5]	4 [3-5]		0.99
Duration of analgesia (hour, median [IQR])	3.95 [2.13-6.44]	5.14 [3.08-7.58]		<0.001
Duration second stage of labour (hour, median [IQR])	0.42 [0.18-0.85]	0.57 [0.25-1.00]		0.005

RAVEL trial

Studies in Obstetrics, Fertility & Gynaecology

LUMC ZonMw

Maternal outcome

	Remifentanil PCA N=447	Epidural analgesia N=347	RR (95% CI)	p value
Fetal condition at start pain relief (CTG)				
Optimal	400 (90.1%)	315 (90.8%)		0.75
Not optimal	44 (9.9%)	32 (9.2%)		
Meconium stained amniotic fluid	46 (10.3%)	46 (13.3%)	0.88 (0.71-1.09)	0.22
Augmentation with oxytocin	293 (65.8%)	246 (70.9%)	0.91 (0.80-1.03)	0.13
>24 hours ROM	31 (7.0%)	30 (8.6%)	0.90 (0.70-1.16)	0.38
Mode of delivery				
Spontaneous	311 (69.6%)	236 (68.0%)	1.03 (0.90-1.18)	0.64
Vaginal instrumental	54 (12.1%)	47 (13.5%)	0.94 (0.77-1.14)	0.53
Caeserean section	82 (18.3%)	64 (18.4%)	0.99 (0.84-1.16)	0.88