

**Comparing 200 µg and 400 µg
sublingual misoprostol for
cervical priming prior to first
trimester surgical abortion; a
Dutch single center clinical pilot**



FIAPAC 2016

Quality Guideline NGvA

March 2015

- Consider priming with misoprostol in all first trimester surgical abortions. Involve parity, age and the patient wish
- Prime always with misoprostol in surgical abortions ≥ 9 weeks of gestation

Pilot Objective

- 200 µg misoprostol sublingual is as effective as 400 µg misoprostol sublingual. No difference in cervical dilatation.
- 200 µg misoprostol sublingual shows fewer side effects comparison to 400 µg misoprostol sublingual.

Population

- Women requesting a surgical abortion between 5 -13 weeks of gestation
- Allocated dose of misoprostol (200 µg or 400 µg) sublingual was self-administered 1 hour prior to treatment
- Vacuum aspiration performed under local or intravenous (general or Ultiva) anaesthesia
- Exclusion: breastfeeding and any contraindication for misoprostol

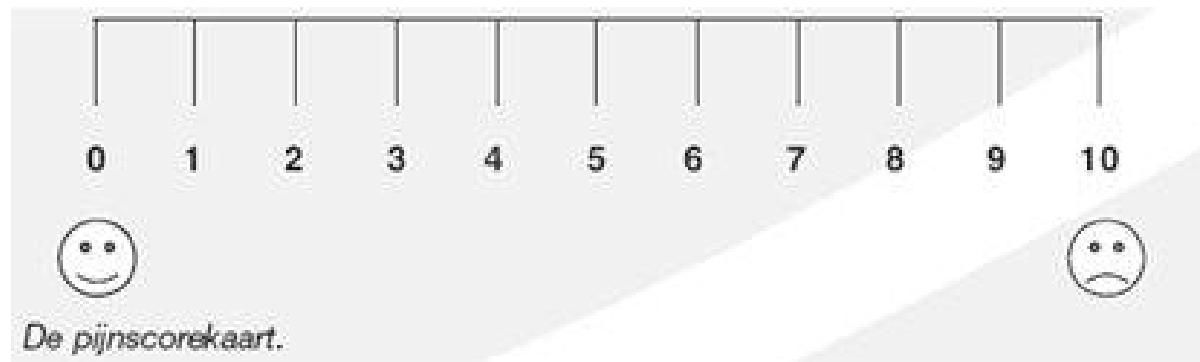
Primary outcome: efficacy parameter

- Cervical dilatation:
The complexity of the procedure
- on a scale from 1 to 5.

1 very stiff / 2 stiff / 3 normal / 4 flexible / 5 very flexible

Secondary outcome: Side effects

- Spontaneously reported
- Pain registration by VAS; before, during and after treatment



Registration Form

Case Report Form MISO Trial

Clíent nummer:

Leeftijd:

G: P: APLA: Sectio:

AM:

Anesthesie: Lokaal / Intraveneus

Misoprostol: 1 / 2

Meetpunt 1 - vlak voor de behandeling:

Heeft u momenteel ergens last van? Indien ja, waar van:

.....

Hoe scoort u de eventuele buikpijn die u momenteel mogelijk ervaart:



De pijnscorekaart.

Meetpunt 2 - verwachte pijn score behandeling. Niet voor cliënten met intraveneuze anesthesie



De pijnscorekaart.

Meetpunt 3 - de behandeling. Niet voor cliënten met intraveneuze anesthesie



De pijnscorekaart.

Hoe verliep de dilatatie : 1 zeer stug / 2 stug / 3 normaal / 4 soepel / 5 heel soepel

Naam behandelend arts:

Meetpunt 4 - direct na de behandeling



De pijnscorekaart.

Meetpunt 5 - vlak voor het ontslag



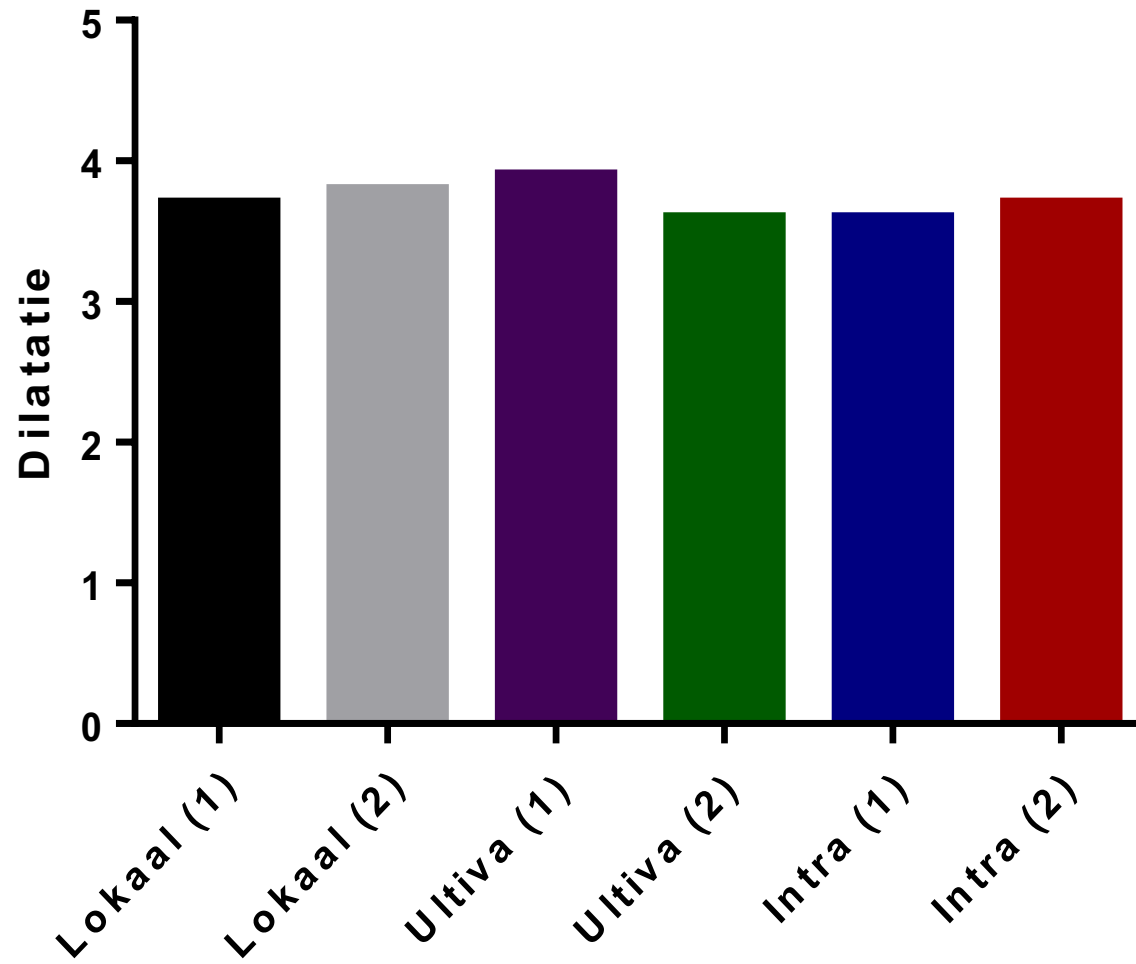
De pijnscorekaart.

Main results

October 2014 - June 2015

	<u>Local (1)</u>	<u>Local (2)</u>	<u>Ultiva (1)</u>	<u>Ultiva (2)</u>	<u>Total(1)</u>	<u>Total (2)</u>
<i>Included</i>	45	46	16	18	99	90
<i>Average age</i>	32,7	31,5	31,6	29,7	25,6	26,3
<i>Average gestation</i>	46,8	49,0	54,9	52,4	59,0	58,2
<i>Average G</i>	3,4	2,8	2,8	2,3	2,5	2,3
<i>Average P</i>	1,7	1,3	1,3	0,9	0,9	0,9
<i>Average APLA</i>	0,5	0,3	0,3	0,3	0,4	0,3
<i>Average Sectio</i>	0,2	0,2	0,3	0,2	0,1	0,1

Miso Pilot Dilatatie

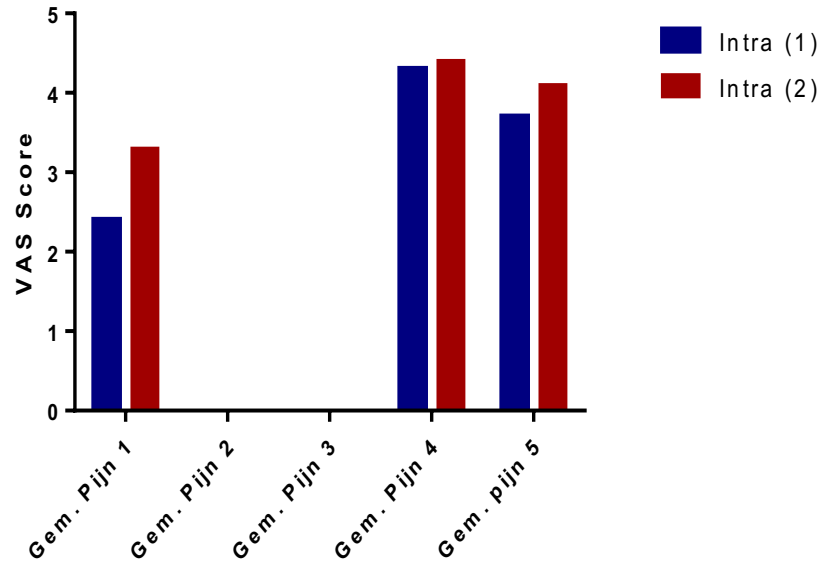


Behandeling Miso 1 vs Miso 2

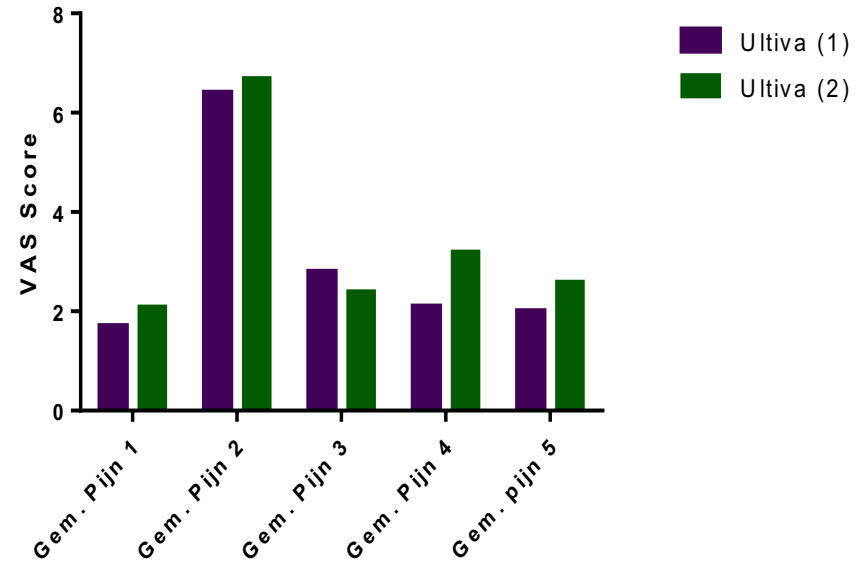
Side effects

	MISO 1	MISO 2
Total side effects	145	162
Abdominal pain	91	92
Shivering	13	19
Throat / mouth	15	17
Nausea	7	16
Dizzy	5	4
Remaining	14	14
No side effects	46	29

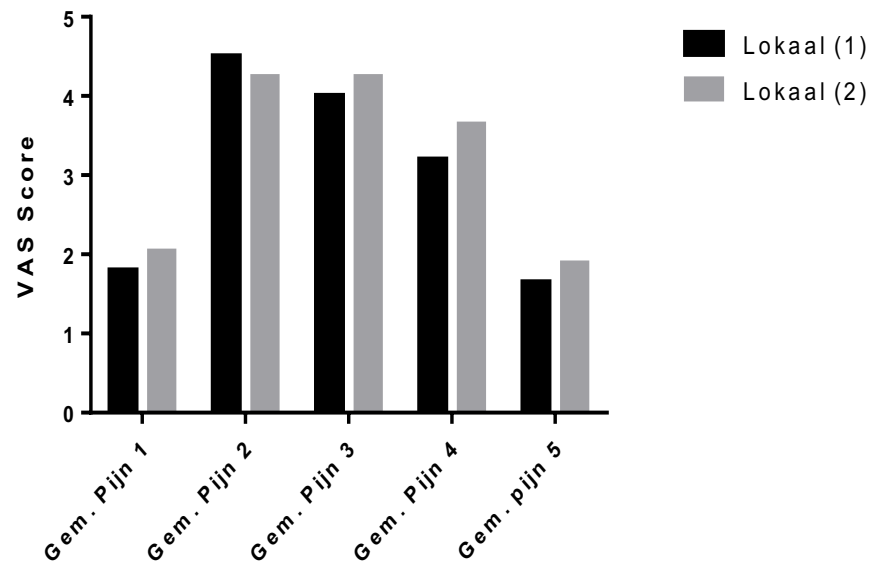
Miso Pilot (Intra, Pijn)



Miso Pilot (Ultiva, Pijn)



Miso Pilot (Lokaal, Pijn)



Conclusion

This pilot indicates 200 µg misoprostol can be used for cervical priming prior to first trimester surgical abortion as the results showed fewer side effects but no difference in cervical dilatation in comparison to 400 µg misoprostol

Limitations

- Efficacy measurement
- Double blind
- Complication follow up

- Randomized, doubleblind, multicentre trial