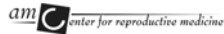


Immobilisation versus immediate mobilisation after intra-uterine insemination; a randomised controlled trial

IM Custers¹, PA Flierman², P Maas³, T Cox³, HJHM van Dessel⁴, MA Gerards⁵, MH Mochtar¹, CAH Janssen⁵, F van der Veen¹, BWJ Mol^{1,7}

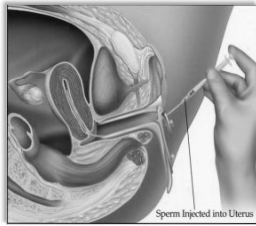
¹Academic Medical Centre, ²Onze Lieve Vrouwe Gasthuis, ³Antonius Hospital, ⁴TweeSteden Hospital, ⁵Groene Hart Hospital ⁶Martini Hospital and ⁷Maxima Medical Centre



Introduction

The Cochrane Library Evidence for healthcare decision-making

- [Intra-uterine insemination for unexplained subfertility](#)
DE Verhaeg, BJ Collins, E Hughes, S de Zeeuw, BJ Heisterkamp
 Year 2006
 Issue 3
- [Intra-uterine insemination for male subfertility](#)
AJ Barendse, BJ Collins, BJ Heisterkamp
 Year 2006
 Issue 3
- [Appropriate insemination versus fallopian tube sperm perfusion for non-tubal infertility](#)
Agar, C, Collins, BJ, Heisterkamp, BJ
 Year 2006
 Issue 3
- [Central insemination versus intra-uterine insemination of donor sperm for subfertility](#)
OF Bawa, C Fung, JH Koster, J Bhargava, P D'Souza
 Year 2006
 Issue 3
- [In vitro fertilisation for unexplained subfertility](#)
Zhou, S, Bhargava, S, Van, A, Sills, A
 Year 2006
 Issue 3
- [Ovarian stimulation protocols \(anti-androgens, gonadotrophins with and without GnRH agonists/antagonists\) for men](#)
Agar, C, Collins, BJ, Heisterkamp, BJ
 Year 2006
 Issue 3
- [Single versus double intra-uterine insemination \(IUI\) in stimulated cycles for subfertile couples](#)
Agar, C, Collins, BJ, Heisterkamp, BJ
 Year 2006
 Issue 3



Unresolved issue: supine position or immediate mobilisation?



PICO-question

- Primair subfertil paar
- Man 33 jaar; vrouw 34 jaar
- 26 maanden bezig
- OFO normaal (VCM 42 milj; PCT normaal)
- Diagnose: subfertiliteit e.c.i.
- Behandelplan: IUI met milde stimulatie
- 10 minuten blijven liggen of opstaan



A randomized study of the effect of 10 minutes of bed rest after intrauterine insemination

Ahmed Saleh, F.R.C.S.C., Seang Lin Tan, M.R.C.O.G., Maririko M. Bijan, M.R.C.O.G., and Togas Tulandi, F.R.C.S.C.

Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, McGill University, Montreal, Quebec, Canada

Objective: To evaluate the effects of 10 minutes of bed rest after intrauterine insemination (IUI) on the pregnancy rate.

Design: Prospective randomized study.

Setting: University teaching hospital.

Patient(s): One hundred sixty couples with unexplained infertility.

Intervention(s): Patients were prospectively randomized either to immediate mobilization after IUI (group I) or to remain in a supine position for 10 minutes after the procedure (group II).

Main Outcome Measure(s): Cumulative pregnancy rate.

Result(s): Ninety-five couples were included in the analysis. Group I consisted of 40 couples (90 cycles), and group II consisted of 55 couples (120 cycles). The pregnancy rate per couple in group I (4 of 40 [10%]) was significantly lower than in group II (16 of 55 [29%]). The pregnancy rate per cycle in group I (4.4%) was also lower than in group II (13.3%). With use of life-table analysis, the cumulative probability of pregnancy in group II was significantly higher than in group I.

Conclusion(s): A 10-minute interval of bed rest after IUI has a positive effect on the pregnancy rate. We recommend that mandatory bed rest for 10 minutes after IUI should be adapted into a standard practice. (Fertil Steril® 2000;74:509–11. ©2000 by American Society for Reproductive Medicine.)

Key Words: Intrauterine insemination, unexplained infertility, bed rest, pregnancy rate

Introduction

A randomized study of the effect of 10 minutes of bed rest after intrauterine insemination

Ahmed Saleh, F.R.C.S.C., Seang Lin Tan, M.R.C.O.G., Maririko M. Bijan, M.R.C.O.G., and Togas Tulandi, F.R.C.S.C.

Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, McGill University, Montreal, Quebec, Canada



Introduction

Comparison between patients mobilized immediately after IUI (group I) and those who remained in supine position for 10 minutes after the procedure (group II).

	Group I (Immediate mobilization) (n = 40)	Group II (Supine for 10 minutes) (n = 55)
Age (y)	32.8 ± 3.2	32.8 ± 3.2
Duration of infertility (mo)	25.7 ± 8.8	25.0 ± 7.8
Primary infertility (%)	38 (95)	40 (73)
No. of cycles	90	120
No. of cycles per couple	2.3 ± 0.8	2.1 ± 0.8
No. of follicles ≥18 mm	1.2 ± 0.3	1.2 ± 0.4
Endometrial thickness (mm)	7.50 ± 1.5	7.50 ± 1.5
No. of viable spermatozoa measured at the 1st insemination (×10 ⁶)	41.0 ± 28.8	41.0 ± 30.1
No. of viable spermatozoa measured at the last insemination (×10 ⁶)	27.6 ± 24.1	24.0 ± 18.6
Pregnancy rate per cycle (%)	4.4	13.3*
Cumulative pregnancy rate (%)	10.0	29.0*

Values are mean ± SD.

*P < .05 compared with group I.

Table. 10 minutes of bed rest after IUI. Fertil Steril 2000.



	Pregnant	Not pregnant	
Rest	16	104	13.3%
Move	4	86	4.4%

NNT = $1 / (13.3\% - 4.4\%) = 11$ cycli blijven liggen voor
1 extra zwangerschap

95% betrouwbaarheidsinterval 6 tot 68

Objective

- Assess the effect of 15 minutes of immobilisation versus immediate mobilisation after Intra Uterine Insemination

Study design

Multi centre trial
7 clinics



Study design

- Inclusion criteria:
 - All patients with an indication for IUI
 - With fresh or cryo-preserved sperm (donor or husband's)
 - With or without controlled ovarian hyperstimulation
 - Anovulatory women: after failed ovulation induction
 - At least one patent tube
 - At least 18 years of age

Study design

- All couples underwent basal fertility work up
 - Diagnosis male factor subfertility: TMC < $10 \cdot 10^6/\text{mL}$
 - Cervical factor: no *progressive* spermatozoa in (at least one well-timed) PCT (TMC > $10 \cdot 10^6/\text{ml}$)
 - Unexplained subfertility: PCT positive, progressive and TMC > $10 \cdot 10^6/\text{ml}$

Study design

- Informed consent obtained
- Randomisation by computer
 - Before the first insemination
 - Stratification: female age and centre
- Parallel design
- Three consecutive cycles in supine position after IUI or three cycles immediate mobilisation

Study design

- Procedure IUI:
 - COH with:
 - Clomiphene citrate
 - r/uFSH
 - No COH
- Timing of ovulation with 5000 IU HCG
- Insemination of 0,3-1,0 mL of processed spermatozoa
- Insemination in lithotomy position with Trendelenburg tilt

Validity

- Randomisation
- Blinding of allocation (concealment)
- Blinding of endpoint
 - Patienten / doctors / observers
- Follow-up
- Intention to treat analysis

Comparable groups?



Randomisation

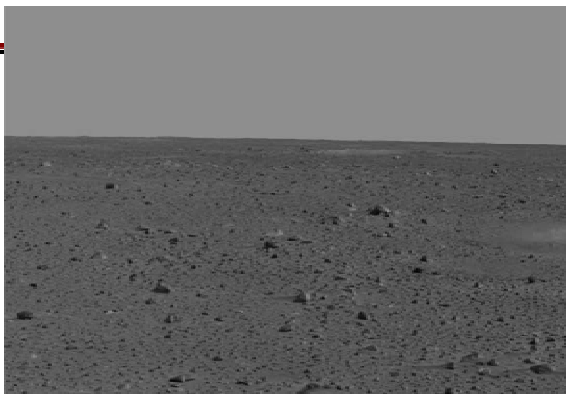


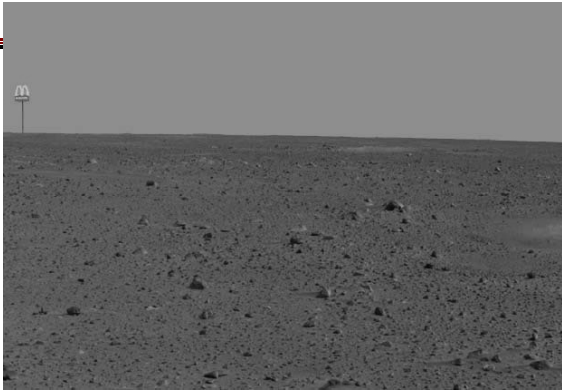
Randomisation

- Envelopes
- Computers
- Webbased
- Telephone

- Independent party

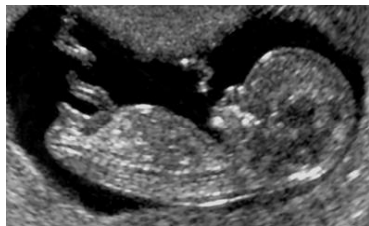
- Concealment





Follow up

- 3 cycles of IUI (max. of 4 months) or
- ongoing pregnancy (12 weeks gestation)



Outcome measures

- Primary outcome measure
 - Ongoing pregnancy rate per couple
- Secondary outcome measures
 - Live birth rate
 - Pregnancy rate per cycle
 - Multiple pregnancies
 - Miscarriages
 - Ectopic pregnancies
 - Biochemical pregnancies



Power calculation

- Testing the 0-hypothesis
- Alpha-error beta-error
- Equivalence study
- Lasagna's law

Power calculation

- Increase of 4% per cycle (= 12% per couple),
- A dropout rate of 10%
- 185 couples per arm
(one-sided test, α -error of 0.05, β -error of 0.20).

Analysis

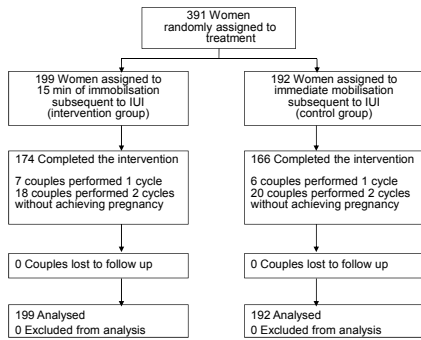
- Intention to treat principle
- Primary and secondary outcome measures expressed in PR per couple and RR with 95% CI

Logistics

- Research nurses
- Data collection

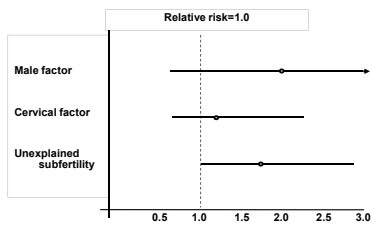
Results

Trial profile



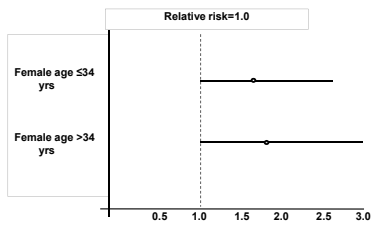
Results

Outcome measures, subgroup analysis



Results

Outcome measures, subgroup analysis



Conclusions

- Immobilisation after IUI leads to increased ongoing pregnancy rates
- Immobilisation should be incorporated in IUI guidelines
