

The New England Journal of Medicine
ABSTRACT
Oil-Based or Water-Based Contrast for
Hysterosalpingography in Infertile Women

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BACKGROUND

Pregnancy rates among infertile women have been reported to increase after hysterosalpingography, but it is unclear whether the type of contrast medium used (oil-based or water-soluble contrast) influences this potential therapeutic effect.

METHODS

We performed a multicenter, randomized trial in 27 hospitals in the Netherlands in which infertile women who were undergoing hysterosalpingography were randomly assigned to undergo this procedure with the use of oil-based or water-based contrast. Subsequently, couples received expectant management or the women underwent intrauterine insemination. The primary outcome was ongoing pregnancy within 6 months after randomization. Outcomes were analyzed according to the intention-to-treat principle.

RESULTS

A total of 1119 women were randomly assigned to hysterosalpingography with oil contrast (557 women) or water contrast (562 women). A total of 220 of 554 women in the oil group (39.7%) and 161 of 554 women in the water group (29.1%) had an ongoing pregnancy (rate ratio, 1.37; 95% confidence interval [CI], 1.16 to 1.61; $P<0.001$), and 214 of 552 women in the oil group (38.8%) and 155 of 552 women in the water group (28.1%) had live births (rate ratio, 1.38; 95% CI, 1.17 to 1.64; $P<0.001$). Rates of adverse events were low and similar in the two groups.

CONCLUSIONS

Rates of ongoing pregnancy and live births were higher among women who underwent hysterosalpingography with oil contrast than among women who underwent this procedure with water contrast.

(Netherlands Trial Register number, NTR3270.)

Multicenter (27) + RCT → 1119 subfertile women

Primary endpoint: Ongoing pregnancy rates within 6 months after randomization (OSCM vs WSCM)

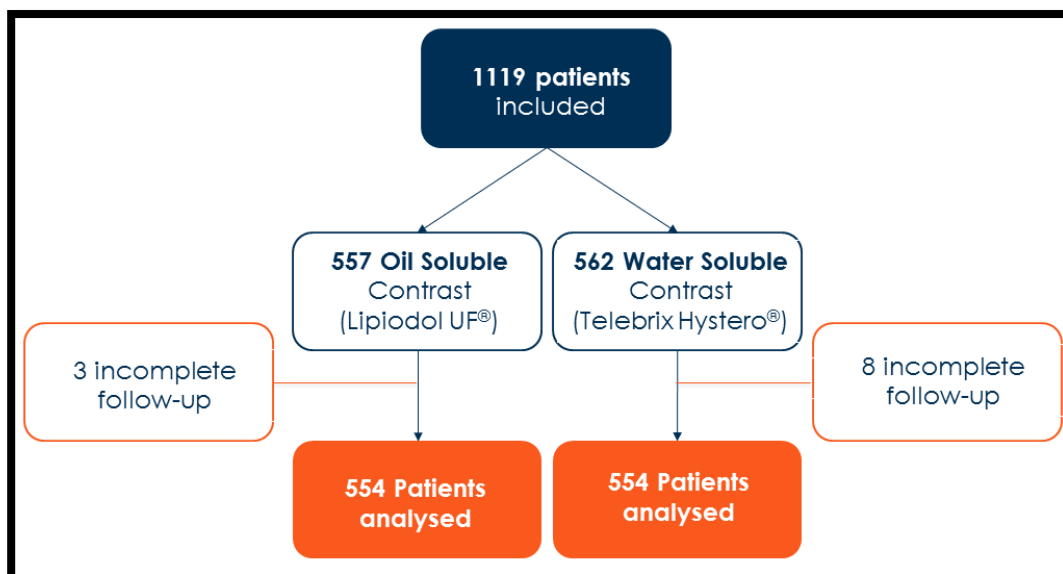
Secondary endpoint: Clinical pregnancy, live birth rates, miscarriages, ectopic pregnancies, pain scores

HSGs performed according to local protocol

- Randomization:

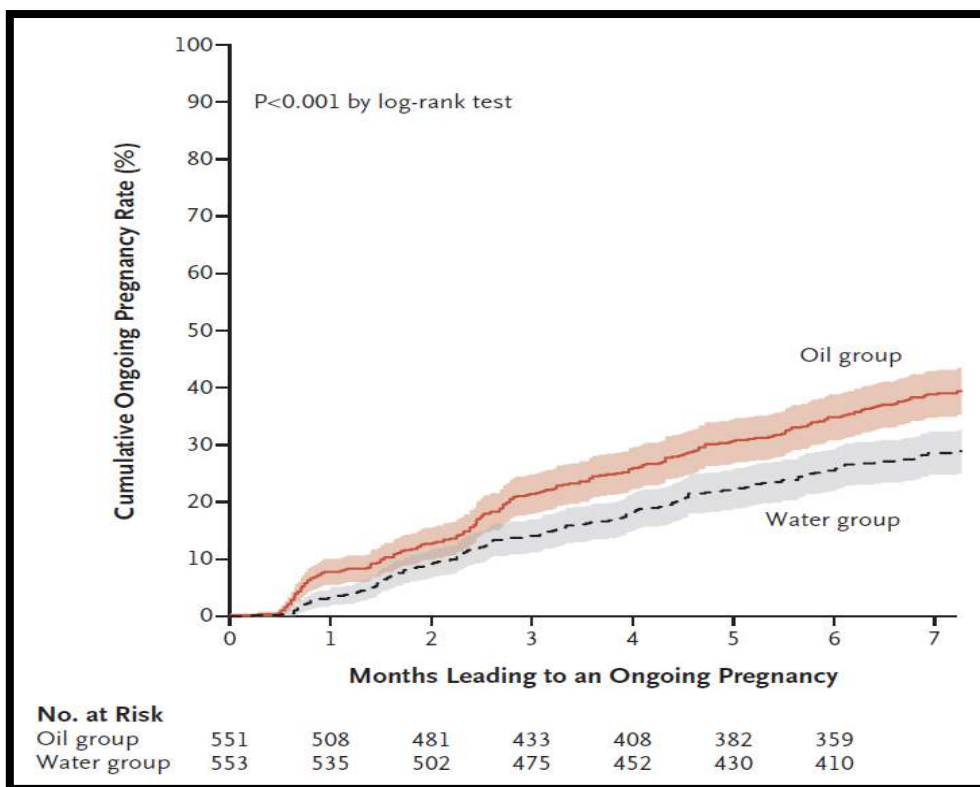
WSCM (Telebrix Hystero) or OSCM(Lipiodol) just before HSG

- Infusion by cervical vacuum cup, metal cannula (hystrophore), or balloon catheter
- 5 to 10 ml of contrast medium
- 4 to 6 radiographs to check tubal patency
- Assessed by radiologist or gynaecologist



INCLUSION CRITERIA	EXCLUSION CRITERIA
☐ Women between 18-39 yrs ☐ Spontaneous menstrual cycles ☐ Trying to conceive for at least 1 year ☐ Valid indication for tubal patency testing by HSG	☐ Endocrinological disease ☐ Less than eight menstrual cycles per year ☐ Known or high risk for tubal pathology ☐ Known contrast (iodine) allergy ☐ Male subfertility (TMSC < 3 x10⁶ spermatozoa/mL)

Results	OSCM group (N=554)	WSCM group (N=554)	Rate Ratio (95% CI)	Comments
Ongoing pregnancy rate	220 (39.7%)	161 (29.1%)	1.37 (1.16 – 1.61) p < 0.001	Primary Endpoint
Clinical pregnancy — no. (%)	251 (45.3)	194 (35.0)	1.29 (1.12–1.50)	Secondary End Points
Miscarriage — no. (%)	29 (5.2)	31 (5.6)	0.94 (0.57–1.53)	
Ectopic pregnancy — no. (%)	2 (0.4)	2 (0.4)	1.00 (0.14–7.07)	
Live birth ≥24 wk of gestation — no./total no. (%)	214/552 (38.8)	155/552 (28.1)	1.38 (1.17–1.64)	



Conclusion

- In infertile couples: HSG with OSCM leads to significantly higher ongoing pregnancy rates during first 6 months compared to WSCM
- Flushing tubes with OSCM should be offered to sub-fertile women as part of fertility workup