

APOSTEL 8 study

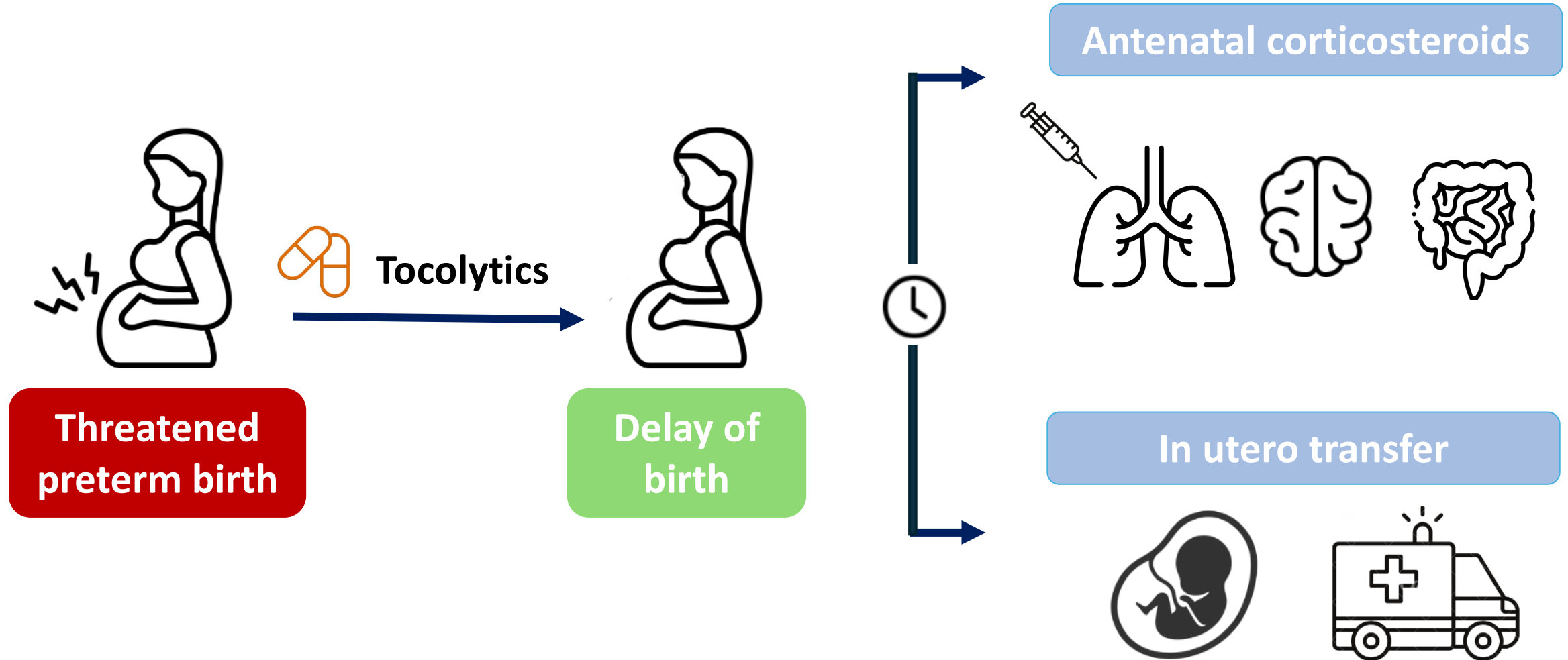
Atosiban versus placebo
for threatened preterm birth:
a multicentre, randomized controlled trial

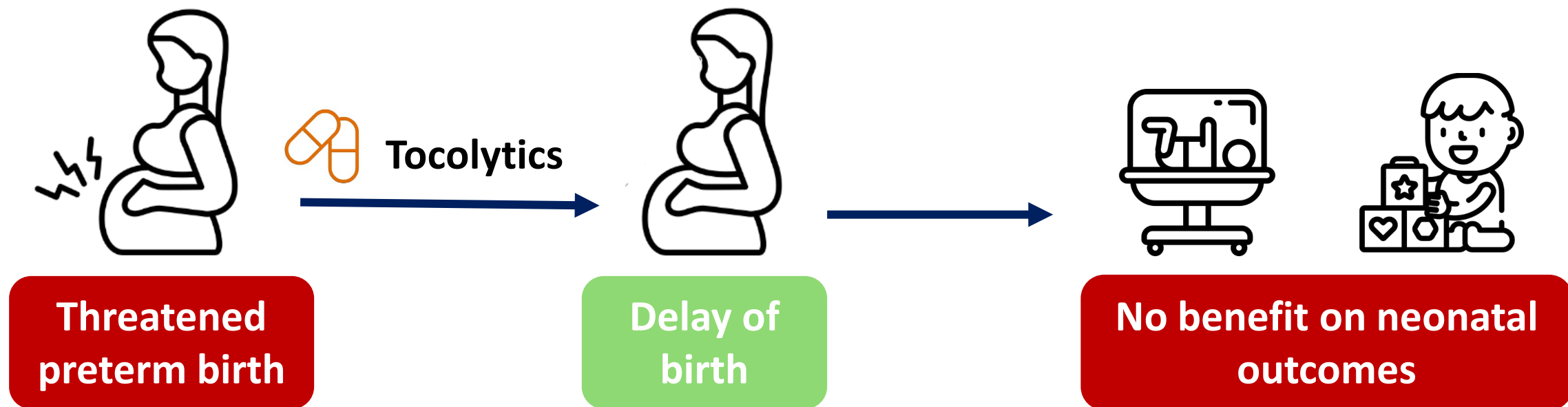
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DISCLOSURE OF INTEREST

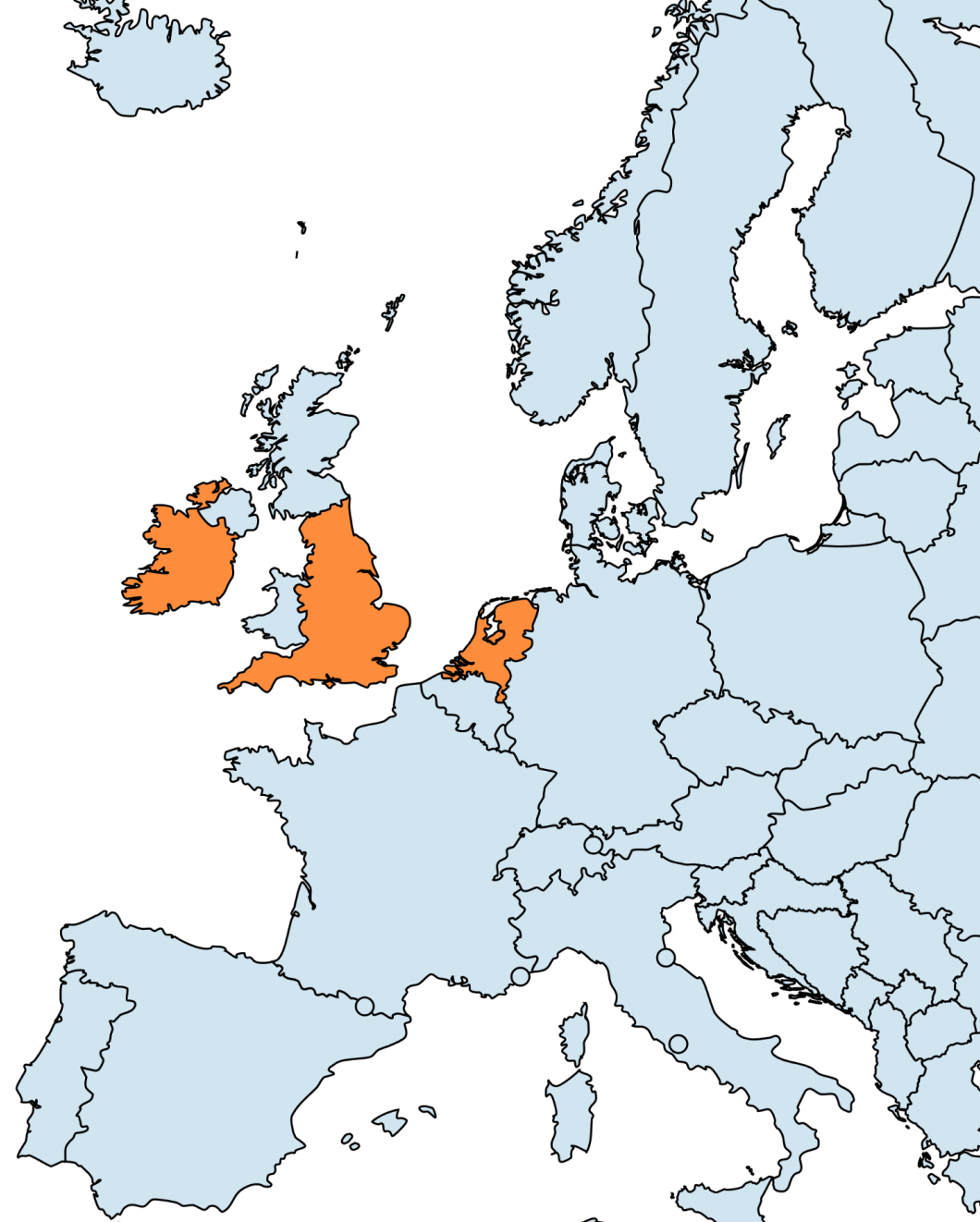
Potential conflict of interest speaker	
Potentially relevant relationships with companies – relevant for this meeting	None
Sponsoring or research funding, co- financing	ZonMw 837002406 (The Netherlands Organization for Health Research and Development)
Honorarium or other financial compensation	None
Shareholder	None
Other relationship: (please enter here)	None





To assess **superiority** of tocolysis with
 atosiban compared to **placebo**
in threatened preterm birth between
30 and 34 weeks' gestation in improving
 neonatal morbidity and mortality

- International
- Double-blind
- Superiority
- Randomized controlled trial
- 26 hospitals
- The Netherlands, England, Ireland





INCLUSION CRITERIA



Singleton or



Twin pregnancy



Threatened preterm birth 30⁺⁰ to 34⁺⁰ weeks

Primary outcome composite of adverse neonatal outcomes

Secondary outcomes: obstetric, neonatal, maternal outcomes



December 2017 – June 2023



755 participants randomized

	Atosiban N = 449	Placebo N = 435	Relative Risk (95% CI)
Composite adverse neonatal outcome	37 (8.2%)	40 (9.2%)	0.90 (0.58 to 1.40)



Atosiban did not reduce adverse neonatal outcomes compared to placebo



Questions the standardized use of tocolytics for threatened PTB between 30 and 34 weeks gestation



Challenges in performing obstetric trials



Reduce unnecessary obstetric interventions



- National preterm birth protocol
- NVOG quality circle from research to implementation
- Multicenter aspect of the trial
- Close contact between projectgroup and members of guideline committee
- Example VVOG
- How to impact the rest of the world?



APOSTEL 9

Evaluation at lower gestational ages < 30 weeks



APOSTEL 8 follow-up

Evaluation long-term child outcomes 4-6 years

Team work, persistence, involved project members and research support and the NVOG consortium make trials succeed!

The Netherlands:

- Amsterdam University Medical Centre
- Amphia Hospital
- Diakonesse Hospital
- Flevo Hospital
- Franciscus Hospital
- Gelre Hospital
- Isala Hospital
- Leiden University Medical Centre
- Maastricht University Medical Centre
- Martini Hospital
- Maxima Medical Centre
- Medical Centre Leeuwarden
- Medical Spectrum Twente
- Onze Lieve Vrouwe Gasthuis
- Radboud University Medical Centre
- Spaarne Gasthuis

- Tergooi Hospital
- University Medical Centre Groningen
- University Medical Centre Utrecht
- Ziekenhuisgroep Twente
- Zuyderland Hospital

England:

- Nottingham University Hospitals NHS Trust

Ireland:

- National Maternity Hospital Dublin



Prof. Dr. Martijn Oudijk



Dr. Carolien Roos



Prof. Dr. Joris van der Post



Dr. Marjolein Kok



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