

Referral for Fetal Therapy for Spina Bifida. The Dutch Way.

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Sils 2015



European topography



17 million inhabitants

The Netherlands

Tertiary care is divided over 8 university hospitals spread over the country



Fetal therapy

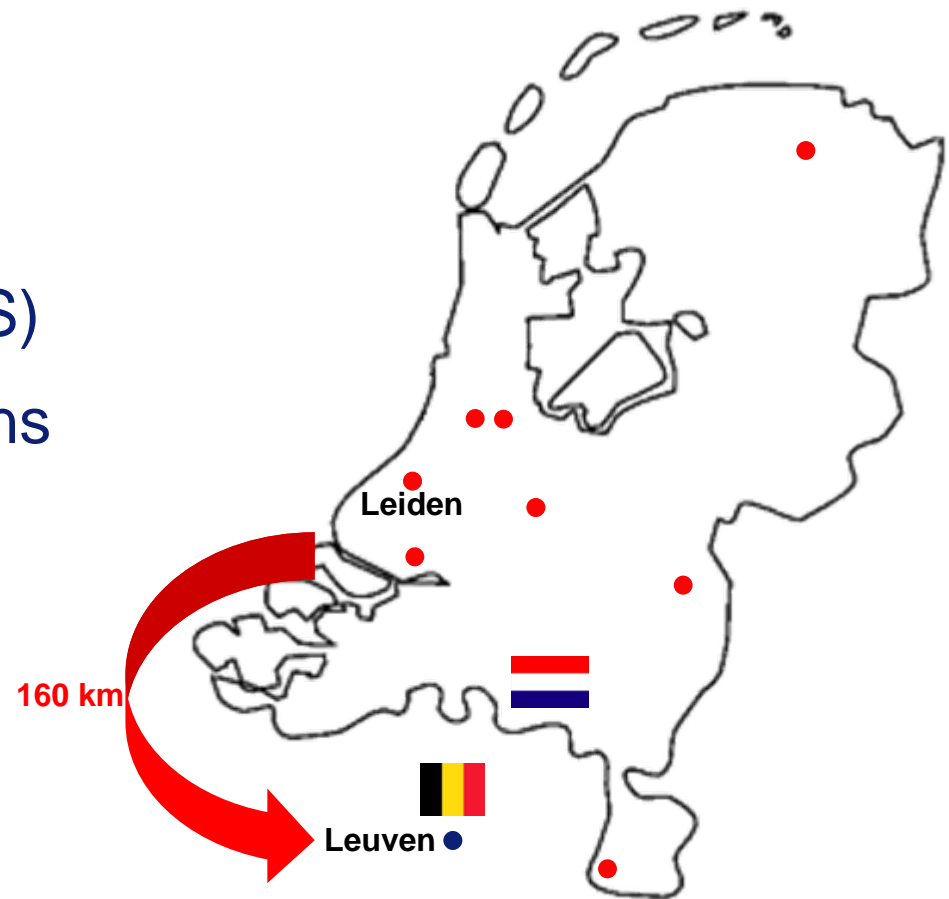
Centralized at UMC of Leiden

Focus on:

- fetoscopic procedures (TTTS)
- intrauterine blood transfusions
- shunt placement (LUTO)
- cardiac procedures

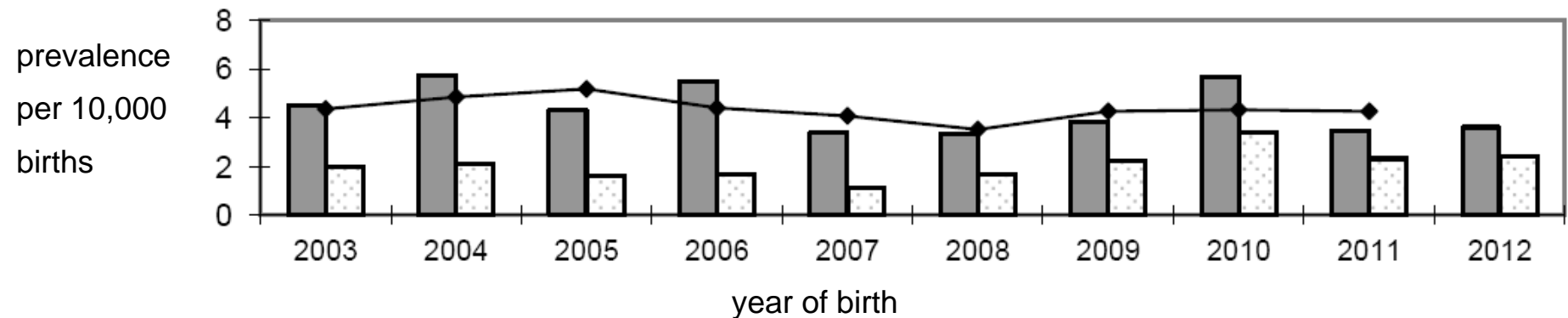
Leuven (B)

- congenital diaphragmatic hernia
- spina bifida



Spina bifida

- Prevalence of isolated spina bifida is 3.5 per 10.000 births
No significant difference per year over the last ten years
- About 20 children with spina bifida are born per year



Spina bifida (non-genetic), 2003-2012

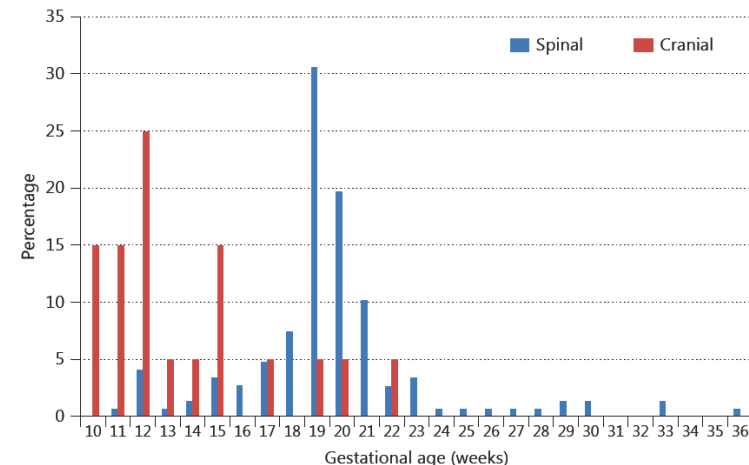
■ total □ terminated pregnancies ● 3-year moving average

source: Eurocat Update: Actual numbers congenital anomalies in Northern Netherlands 2014

Spina bifida

- Introduction of the routine 20-week ultrasound scan 2007
 - number of prenatally detected spina bifida increased to 95%
 - number of elective terminations < 24 wks increased
(EMC 75% TOP, independent of the level of the lesion)
- Majority of spina bifida is diagnosed around 20 wks gestation

Gestational age at initial diagnosis for spinal and cranial lesions in Prenatal Diagnosis and Patient Preferences in Patients with Neural Tube Defects around the Advent of Fetal Surgery in Belgium and Holland
Fetal Diagn Ther. 2014 Oct 3
Ovaere, Eggink, Deprest et al.



Prenatal Diagnosis

- Every pregnant women with a low risk for congenital anomalies is offered a screening ultrasound scan at 20 weeks' gestation
- Local primary care centers
- Certified health professionals with ultrasound education (midwives, general practitioners)



Prenatal Diagnosis

Suspicion of the presence of a spina bifida:

- Referral to tertiary center for prenatal diagnosis
 - advanced ultrasound scan
 - genetic testing
 - advanced imaging (3D ultrasound and/or MRI)
 - counseling by a multidisciplinary team of specialists



Counseling

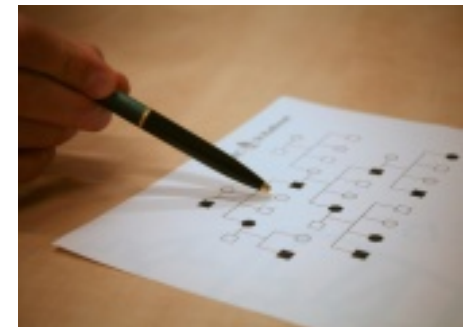
Available options are;

- expectant management
- termination of pregnancy
- fetal surgery

Termination of pregnancy is legal up to 24 weeks of gestation

After 24 weeks restricted;

- lethal condition
- no successful postnatal treatment



Fetal therapy in Leuven

- March 2011 publication of the outcomes of the MOMS trial
 - Start fetal spina bifida repair at the University Hospital in Leuven
 - Fetal therapy for spina bifida available for Dutch patient

The **NEW ENGLAND**
JOURNAL *of* **MEDICINE**

ESTABLISHED IN 1812

MARCH 17, 2011

VOL. 364 NO. 11

A Randomized Trial of Prenatal versus Postnatal Repair
of Myelomeningocele

N. Scott Adzick, M.D., Elizabeth A. Thom, Ph.D., Catherine Y. Spong, M.D., John W. Brock III, M.D.,
Pamela K. Burrows, M.S., Mark P. Johnson, M.D., Lori J. Howell, R.N., M.S., Jody A. Farrell, R.N., M.S.N.,
Mary E. Dabrowiak, R.N., M.S.N., Leslie N. Sutton, M.D., Nalin Gupta, M.D., Ph.D., Noel B. Tulipan, M.D.,
Mary E. D'Alton, M.D., and Diana L. Farmer, M.D., for the MOMS Investigators*

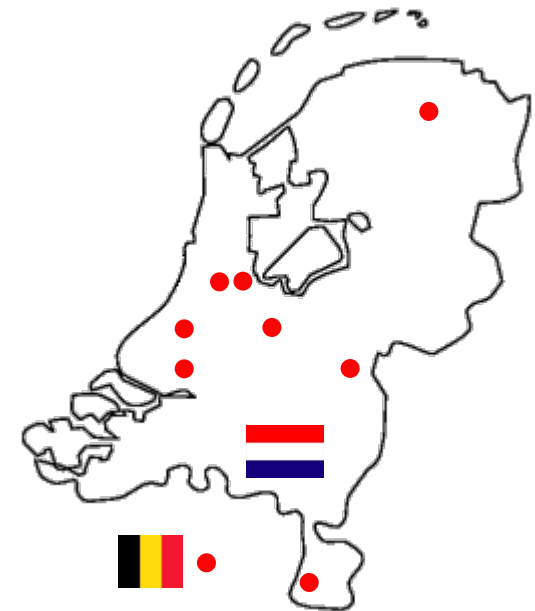
Multidisciplinary consortium PROSPER

PROSPER

PROspective SPina bifida Registry of outcome after intrauterine surgery

The consortium consists of:

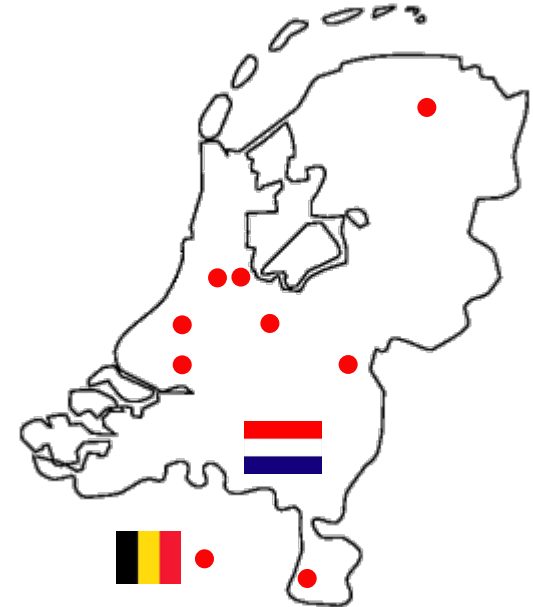
- gynecologists
- pediatric neurologists
- neurosurgeon
- neonatologist
- rehabilitation physician
- ethicist



Statement about open fetal surgery

Open fetal surgery for spina bifida should not take place
in the Netherlands

Patients can be referred to Leuven



Main goals of the PROSPER consortium

- Interpretation of the outcomes of the MOMS trial and translate them to the Dutch situation
- Reach consensus within the various disciplines
- Develop guidelines for counseling and referral
- Develop an information leaflet for patients and counselors
- Start a follow up program for spina bifida patients

Contact with the patient association for people born with a physical disability

Information leaflets available at www.fetusned.nl

Recommendations of the PROSPER consortium

- Counselors should have knowledge of (dis)advantages
- Counseling in a tertiary center and multidisciplinary
- Fetal therapy should be mentioned but without recommendation
- Referral to Leuven will be from a tertiary center and before 22w
- Inclusion criteria should be strictly enforced
- After fetal therapy: follow up and delivery in center of referral
- All patients should be included in a follow up study

Guidelines published in
Fetal therapy for spina bifida
Ned Tijdschr Geneesk. 2012;156(38):A4924
Eggink

Political interest

Recent meeting with Dutch Ministry of Health, Welfare and Sport

- Plea for full reimbursement of medical costs by health insurance companies for referral to leuven
- Request for financial support for further research in minimally invasive techniques
- Start a follow up program for Dutch fetal surgery patients and to explore the possibilities for an European registry

Up to date

9 patients were referred to Leuven for assessment for fetal surgery

3 patients chose the option of fetal surgery and underwent fetal repair

6 patients declined after evaluation and counseling

3 postnatal management

3 termination of pregnancy

Conclusion

Although fetal therapy must not yet be seen as standard care in the Netherlands, the pregnant woman is entitled to full information and must have the possibility to be referred for fetal therapy in case of a prenatally diagnosed spina bifida

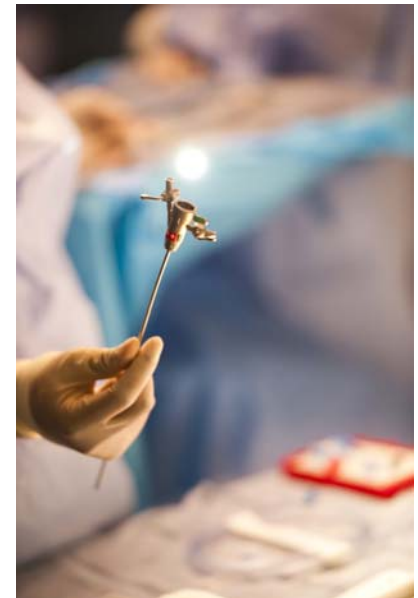


Future perspectives

Since numbers are limited in the fetal surgery program in Europe, we propose;

- Close collaboration
- Uniform international follow up program including an international database

Future studies should also focus on minimally invasive techniques, applied early in pregnancy, using advanced techniques and tissue engineering



Members

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