

# Population Screening Act: NIPT for multiple pregnancies

## Executive summary

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Health Council of the Netherlands



On behalf of the NIPT consortium, Amsterdam UMC - location VU University Medical Center, has applied for a permit to offer the non-invasive prenatal test (NIPT) to women with multiple pregnancies. This supplements two current studies (TRIDENT 1 and 2) on the introduction of the NIPT into prenatal screening for trisomies 21, 13, and 18, the syndromes of Down, Patau and Edwards. The Health Council's Committee on Population Screening has evaluated the permit application against the requirements of the Population Screening Act (WBO).

The application is for various types of multiple pregnancies: dichorionic twins (twins which each have their own placenta and amniotic sac and are almost always dizygotic (non-identical) twins), multiple pregnancies with three or more foetuses, and vanishing twins (twins whereby only one amniotic sac contains an embryo with a heartbeat). In all of these multiple pregnancies, it can be a complicated matter to detect the DNA of the foetuses in the blood of the mother.

Women with these types of multiple pregnancies

were excluded from participating in the NIPT until now.

The committee concludes that the study is scientifically valid and that the benefits outweigh the risks for the pregnant women. The study also has a scientific benefit: it will provide additional data regarding the test characteristics of the NIPT for the above-mentioned types of multiple pregnancies. This is of particular importance now that the combined test will probably be phased out as prenatal screening test over the next few years. The scientific data now available in relation to multiple pregnancies are still limited, which means that there is some uncertainty regarding the test characteristics of the NIPT for these multiple pregnancies. Based on the published data, the committee concludes that the test characteristics of the NIPT for dichorionic twin pregnancies are sufficiently favourable.

The Committee advises the State Secretary for Health Welfare and Sport to grant the permit subject to the following conditions:

- For dichorionic twins and multiple pregnancies with three or more foetuses, the NIPT will be offered as initial test (TRIDENT 2) and the choice will not be offered to first start with the combined test and only after a positive result to switch to the NIPT as follow-up test (TRIDENT 1). The reason for this is that, in case of confirmed trisomy, the optional follow-up procedure (removing the foetus with trisomy) should preferably take place as early as possible in the pregnancy.
- The test characteristics of the NIPT will be monitored for all target groups, in other words for the dichorionic twins, multiple pregnancies with three or more foetuses, and vanishing twin pregnancies. In addition, for all these pregnancies, the outcome of the NIPT and the definitive presence or absence of trisomy will be registered.
- The causes of test failure will be specifically registered, whereby the characteristics of the



pregnant woman and the pregnancy will also be registered.

- The information materials for the pregnant woman will be updated. The material will contain information about the uncertainties of the test characteristics, about the probability of failure of the test, and about the consequences that this could have for them, in order to ensure that the pregnant woman can make a well-informed choice.
- The counsellors will be trained in counselling pregnant women with multiple pregnancies.



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