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## Prospective randomised comparative study of the effect of buprenorphine, methadone and heroin on the course of pregnancy, birthweight of newborns, early postpartum adaptation and course of the neonatal abstinence syndrome (NAS) in women followed up in the outpatient department.

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### Abstract

**OBJECTIVE:** The aim of the study was to evaluate the effect of substitution therapy in heroin addicted pregnant women on the course of pregnancy, perinatal outcomes and course of the neonatal abstinence syndrome.

**DESIGN OF THE STUDY:** A five-year randomised prospective comparative study

**METHODS:** The study was carried out in the period of 2002-2007. The group of patients included 147 i.v. heroin-addicted pregnant women. All of them were outpatients of our Perinatal Care Unit. Their daily dose of heroin was approximately 1g. Later, 30 women were disqualified from the study for breaking the randomised criteria engagement. The substitution therapy in women who agreed to undergo it, started during the I. trimester of pregnancy. Finally, 47 heroin, 32 methadone and 38 buprenorphine addicted women were enrolled in the study. Birthweight of newborns was compared with the national birthweight tables. Severity and duration of neonatal abstinence syndrome (NAS) were evaluated by Finnegan score scale.

**RESULTS:** None of the women delivered before the end of 34th gestational week. We did not encounter any perinatal death or developmental defect. The lowest birthweight, the highest number of newborns with IUGR and the most numerous placental changes were found in the group of heroin-addicted women. The differences compared to the two groups receiving substitution therapy were statistically significant ( $p < 0.05$ ). The severity and course of NAS were the most severe ( $p < 0.001$ ) in newborns of women from the methadone group.

**CONCLUSION:** Comparison of the groups of outpatients is in many ways questionable because of the restricted possibility of the patients' control. The lifestyle of addicted women has the same impact as the drug use alone. This is probably the main reason for differences in some of the monitored parameters between individual groups. Based on our results we can state that substitution therapy provides pregnant women with the possibility of social stabilization and adequate prenatal care. substitution therapy decreases the street heroin consumption. Methadone notably protracts the newborn's abstinence syndrome. With regard to this fact, attention has been recently focused on substitution with buprenorphine that seems to be from this viewpoint a more considerate option.

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