Ethical and regulatory aspects of clinical trials in paediatric population in the Republic of Macedonia

V.Ivanovska[1], B.Angelovska[1], M.Atanasova[1], V.Ivanova[1]

[1] University “GoceDelcev”, Faculty of Medical Sciences, Krste Misirkov bb, POB 201, Stip, R. Macedonia,

Introduction

- Clinical trials in children should be carried out to provide adequate protection whilst recognising the right to benefit from research. Their vulnerability emphasizes the responsibility to ensure parental permission and assent of able children, assurance of direct benefit for the child with the particular condition, minimization of risk, and scientific necessity of the research. Although there may be ethical concerns about conducting paediatric trials, this has to be balanced by the ethical concerns about giving medicines to a population in which they have not been tested. Specific clinical trials in paediatric populations are required due to age-related differences in the drug handling or drug effects which may lead to different formulation or dose requirements to achieve efficacy or to avoid adverse effects

Materials and metods

- Many countries have adopted regulations or guidelines specific to paediatric research. The Directive 2001/20/EC and Regulation 536/2014 have laid down specific requirements in the EU to protect children who take part in clinical trials.
- We aimed to investigate regulations that specify the conduct of clinical trials in children in the Republic of Macedonia.

Results

- The Ministry of Health developed the *Rulebook* for the conduct of clinical trials in 2009. Its articles 9 and 10 specifically regulate the protection of children in Macedonia. They describe the enrollment conditions for children in clinical trials, including the provision of parental permission, child assent and the role of the ethics committee.
- National health authorities have adopted regulation to balance the benefits and risks of research in children in line with the EU regulations.