

EU CHILDHOOD OBESITY PROGRAMME

www.childhood-obesity.org

“The EU Childhood Obesity Programme is investigating whether the protein / fat ratio in infant formula and complementary feeds has lasting effects on obesity risks.”

Project Title: Childhood Obesity: Early Programming by Infant Nutrition?

Project Number: QLK1-CT-2001-00389

Focus on Work Package 6 Recruitment and monitoring of intervention trial

Recruitment

The original aim of the trial was to recruit 1250 babies (1000 formula-fed and 250 breastfed babies) within the first 6 months of the project, starting in October 2002. We needed 200 formula-fed and 50 breastfed infants in each of the five study centres (Germany, Belgium, Italy, Poland and Spain).

Unfortunately, this task has turned out to be more difficult than expected, especially in Germany and Belgium. At the end of 6 months, we had recruited 497 babies, of whom 289 were formula-fed and 208 breastfed. The high breastfeeding rate in the participating countries meant that the recruitment of formula-fed babies has been delayed whereas recruitment of breastfed babies proceeded as planned.

Several remedial measures have been taken (e.g. mailings to paediatricians and midwives in Germany and Belgium, radio transmissions in Spain). Further, the upper boundary of the time window for inclusion of a baby has been increased from 28 days to 56 days of age. In addition, the recruitment period has been prolonged from 6 months to 9 months and a further prolongation will probably be necessary. At the end of 9 months, a further 419 children had been recruited, thus giving a total of 916 infants in the trial, 559 of whom are formula-fed and 357 are breastfed.

Dropout rates from the trial are relatively high: 17.0 % in formula-fed and 28 % in breastfed babies, respectively. Although this dropout can be overcome to a certain extent by supplementary recruitment, we are trying to prevent dropouts by providing

a well-elaborated 'medical service' and by offering appropriate incentives for mothers to stay in the study.

Monitoring

Ours is a double blind randomised clinical trial. In order to ensure quality control according to good clinical practice (GCP) guidelines, clinical monitoring must be performed. For this purpose, each of the 5 study centres must be visited :

- to standardise the understanding of the protocols and case reports forms in different languages in each sites
- to verify the data collection
- to solve emerging questions concerning recruitment, dietary habits and data collection
- to reinforce the ethical conduct of the study

During a site visit, local recruitment places will be viewed, case reports forms monitored and data bases inspected according to standard operating procedures. Interim reports will be made.

Since electronic data capture technology is used, the electronic case reports forms (eCRFs) will be continuously monitored. The central database will then be operated by remote control, so that additional site visits are unnecessary. For this reason one site visit at each study centre for between 2 and 4 days should be sufficient.

General problems with respect to monitoring will be discussed at the 'project co-ordination' meetings (involving all trial leaders) that are organised to coincide with Technical Committee meetings.