Workshop on Immunological Contraceptives (Antifertility 'Vaccines'), 7th International Women and Health Meeting, Kampala,Uganda, 12-l8th September 1993

CLINICAL TRIALS OF IMMUNOLOGICAL CONTRACEPTIVES

Judith Richter

Organisation of the background paper:
1. The five major research coordination centres
2. Maps on clinical trials by coordinating centre (WHO. NII. Pop. Council)
3. Pre-clinical research (& map of additional research teams)

I. THE FIVE MAJOR RESEARCH COORDINATING CENTRES

The World Health Organization. Special Programme of Research. DeveloDment and Research Training in Human Reproduction (WHO/HRP). Geneva:
Coordinator: David Griffin. Manager of the Task Force on Fertility Regulating Vaccines

The National Institute of Immunology (NII). New Delhi:
Coordinator: G.Pran Talwar. Professor of Eminence and former director of the Institute

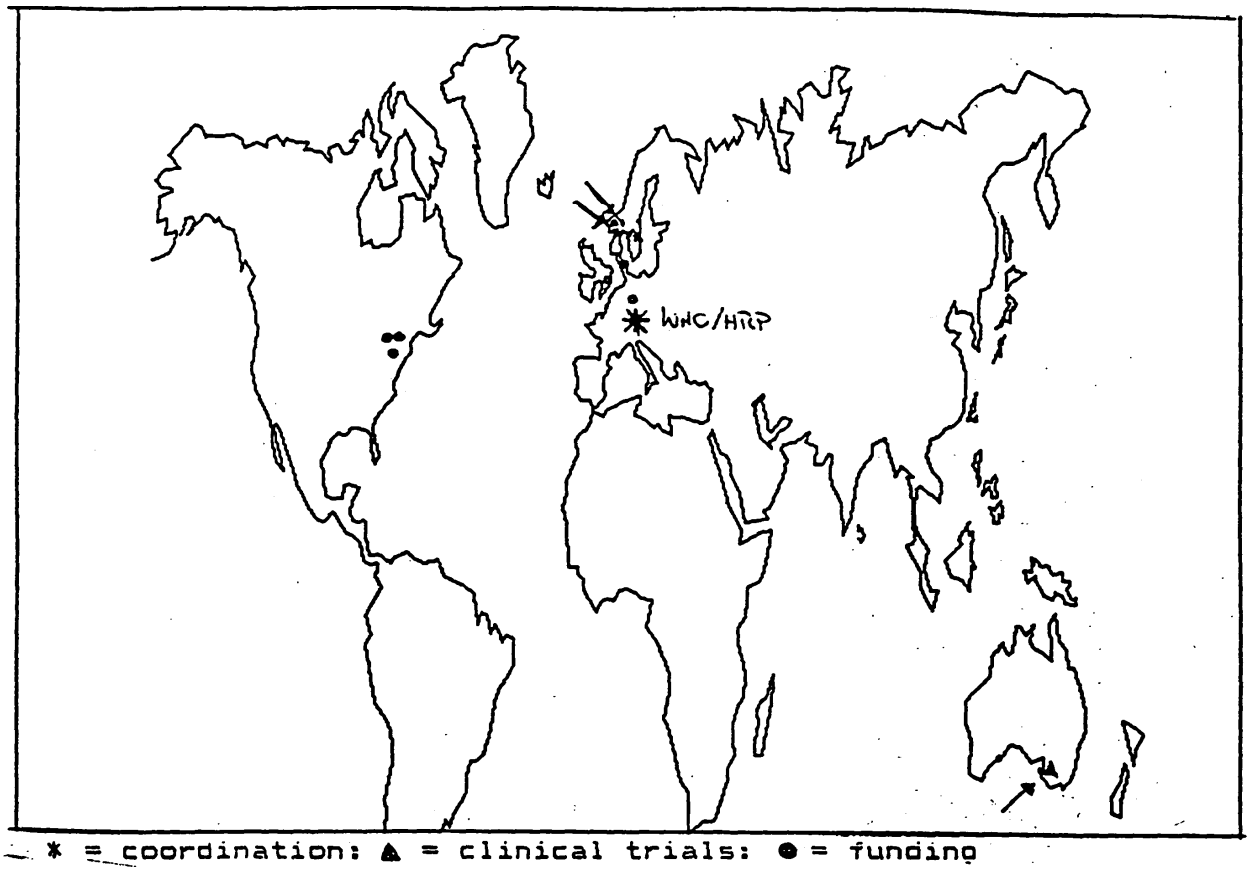
The Population Council. New York:
Coordinator: Rosemary Than, Director of Contraceptive Research

The Contraceptive Development Programme (CONRAD). East Virginia Medical School, in Norfolk, Virginia. U.S.A.
Coordinator: Henry Gabelnick, Program Director?

The National Institute for Child Health and Development/National Institutes of Health (NICHD/NIH), Bethesda, Maryland, U.S.A.
Coordinator: Gabriel Bialy. Chief of the Contraceptive Development Branch of the Centre for Population Research?

II. MAPS ON CLINICAL TRIALS

THE WORLD HEALTH ORGANIZATION
WHO/HRP



Clinical trials:
Prototype anti-hCG contraceptive (beta-hCG-CTP):

– Phase I completed in 1988:
  30 women: Flinders Medical Center, Adelaide, Australia (Warren R. Jones)
– Phase II planned for 1993: **)
  About 200 women: Karolinska Institute, Stockholm, Sweden (S.Cekan?) & University Hospital, Uppsala, Sweden (V.Odlind?).
  NB: Formulation of product by a Swedish company (G.Thorell, Galenus, Uppsala?)

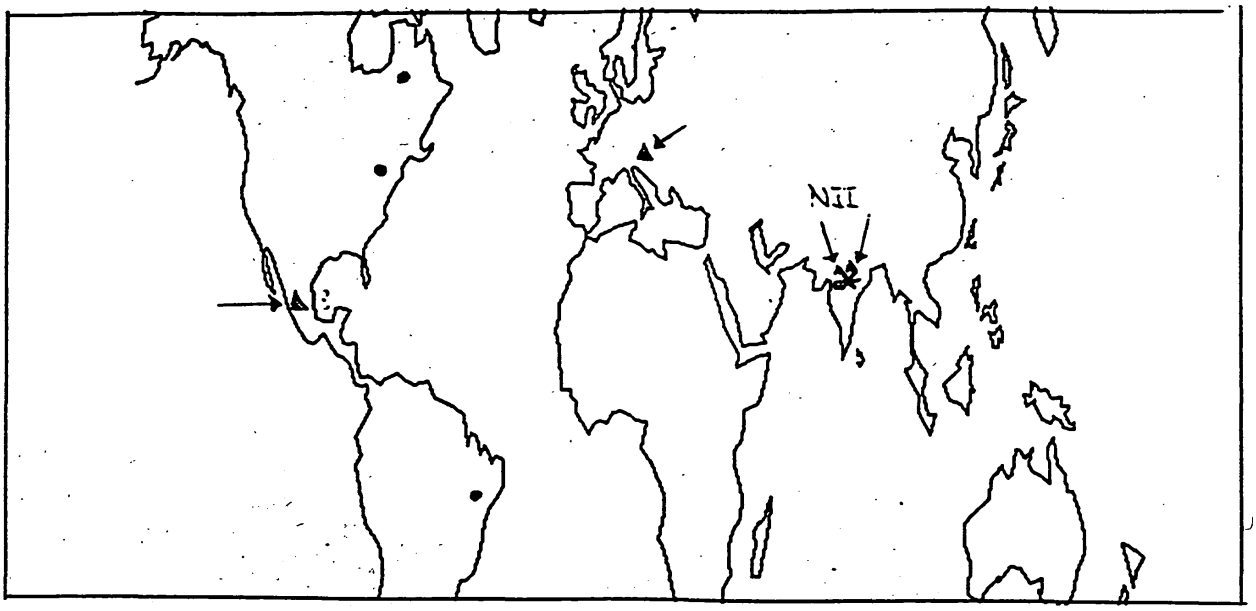
Advanced prototype (i.e. microcapsule formulation):

– Phase I: planned for 1994/5 (in same Swedish Institutes)

Funding:
General HRP funding, i.e. UNDP: UNFPA: World Bank: governments of Denmark, Norway, Sweden. UK, Germany etc.
Phase I of prototype: moreover Sandoz
Phase II: moreover Swedish government (liability coverage)

**) update April '94: about 50 women / the first ones were 'Vaccinated' just recently

THE NATIONAL INSTITUTE OF IMMUNOLOGY
NII



Prototype anti-hCG contraceptive:

- Phase I completed in 1990 (several hCG formulations):
  101 women in 5 Indian centres
- Phase II completed in 1993 (alpha-oLH:beta-hCG):
  Originally planned 180 women, stopped at around 105 women:
  All India Institute of Medical Sciences (AIIMS), New Delhi (K. Buckshee: L. Saraya): Safdarjung Hospital, New Delhi (S.K.Das: S.Suri): Postgraduate Institute of Medical Education and Research, Chandigarh (PGI) (K. Dhall: A.Sarkar).
- Phase III Planned (potentially combined with "phase I/II" trial of intrauterine neem extract administration - Praneem VILCI - for the lag-phase of.immunological contraceptives).

Funding (of phase I & II trials):
Government of India (Science and Technology Project of the Department of Biotechnology): The International Development Research Centre (IDRC) of Canada: The Rockefeller Foundation

Anti-GnRH contraceptive ("to prolong lactational amenorrhoea"):

- Phase I in 1992?:
  At least 20 women, Safdarjung Hospital?: University College of Medical Sciences, both New Delhi, India

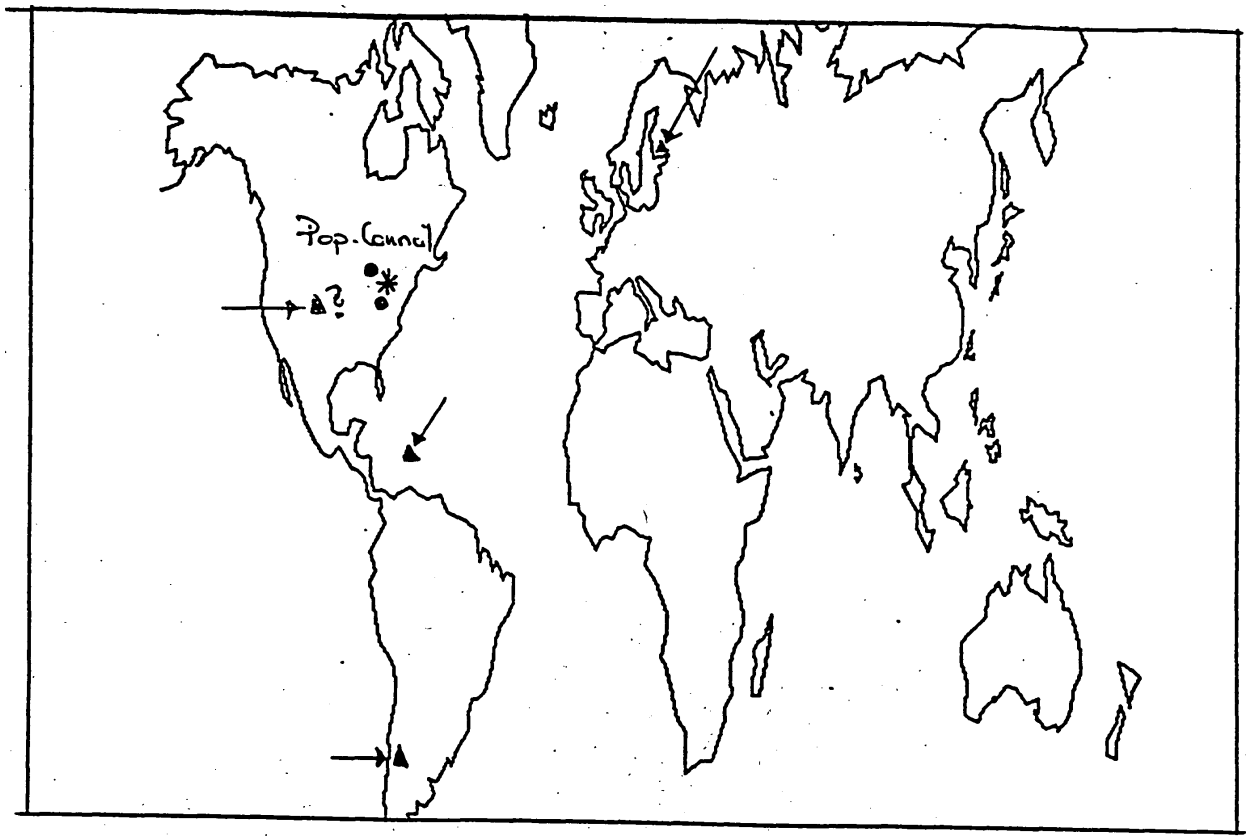
Funding:
South to South Cooperation in Reproductive Health. Salvador, Bahia, Brazil (Rockefeller funded): others?

Anti-GnRH auto-immunization against protstate cancer:

- Phase I:
  ? men. 2 centres in India. 1 in Austria (J. Frick), 1 in Mexico?

Funding: N.D.

THE POPULATION COUNCIL



Anti-hCG immune contraceptive (beta-hCG):

- Phase I study completed in 1991:
  24 women: Instituto Chileno de Medicina Reproductiva, Santiago, Chile (H.Croxatto): University of Helsinki, Finland (T.Luukainen): Association Dominicana Pro Bienestar de la Familia, Santo Domingo, Dominican Republic (F.Alvarez: V.Brache)
- Currently no phase II planned

Funding:

Pop. Council's "programmatic funds" (i.e. Georg J.Hecht Fund: The Andrew W.Mellon Foundation: The Rockefeller Foundation).

Anti-GnRH auto-immunization against prostate cancer:

- "Phase I", 4 (potentially 10 more) men with prostate cancer, unknown trial centre in USA.
  NB: If no major adverse effects, plan to test anti-GnRH formula as male contraceptive for healthy men

Funding: NIH, programmatic funds, USAID, Dodge Foundation

Anti-FSH (oFSH):

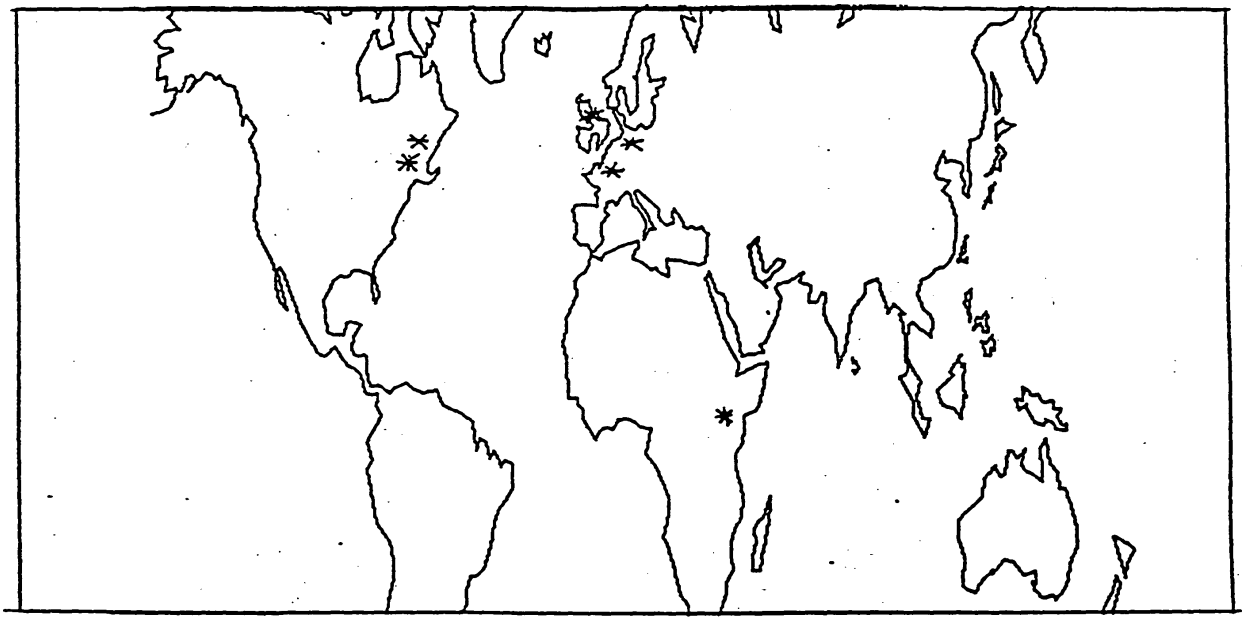
- Phase I planned, trial centres unknown (USA?)

Funding: USAID?

III. PRE-CLINICAL RESEARCH

Before mentioned five organisations are moreover doing laboratory and/or animal studies on:

- Anti-GnRH contraceptive, clinical trial planned by NICHD
- Anti-sperm contraceptives - mainly for women (CONRAD, NICHD. NII, Pop. Council). John Herr, Virginia University, planning human trials in 1995 depending on outcome animal trials (funding: CONRAD)
- Anti-egg immune contraceptive (CONRAD, NII)
- Anti-trophoblast contraceptive (WHP/HRP)



Other research teams (*) include:

- Dominioue Bellet. Institut Gustave-Roussy, France. Focus:
  anti-hCG contraceptive. Planning clinical trials?
- M.R Moudgal, Indian Institute of Science, Bangalore, India.
  Focus: anti-FSH contraceptives in men (potentially already phase I trials (funding: CONRAD: Indian government?)
- John Aitken, Reproductive Biology Unit of Edinburgh University, UK; Jacques Testard, Institut National de la Sante et de la Recherche Medicale (INSERM), France, Focus:
  anti-egg contraceptives.
- Mohamed A.Isahakia & Charanjit S.Bambra, Institute of Primate Research, National Museums of Kenya, Nairobi. Focus:
  anti-sperm and anti-egg contraceptives .(funding: CONRAD).
- Peter M. Johnson, Department of Immunology, University of Liverpool, UK; C.S. Bambra, National Museums of Kenya, Nairobi (funding: e.g. WHO/HRP): ? & ?, Hamburg, Germany.
  Focus: anti-trophoblast contraceptives.

Note: Earlier clinical trials by the Population Council and the National Institute of Immunology (often referred to as “probing clinical trials”) have been left out of this survey. It is difficult to get complete (and consistent) data on some of the clinical trials. The survey should therefore be seen as provisional.