



oro xcell
biopharmaceutical
partner
for life sciences
industries

**In situ gastro-intestinal perfusion
and pharmacokinetic studies in man**

In situ gastro-intestinal perfusion and pharmacokinetic studies in man

1. Pharmacokinetic studies in man

- Clinical pharmacokinetic studies
- Protocol outline
- Timelines

2. Partnership with Avicenne hospital

- Avicenne hospital: Gastro-enterology group
- Avicenne hospital



Clinical pharmacokinetic studies

In partnership with Avicenne hospital



***In situ* gastro-intestinal perfusion**

- Bypassing the stomach
- Specifically targeting an absorption window in the intestine
- Monitoring the active ingredient or formulation behavior in intestinal fluids

Pharmacokinetics

- Fed or fasted conditions
- Concomitant blood sampling for determination of PK parameters

Exclusive offer to understand and solve bioavailability issues

Protocol outline

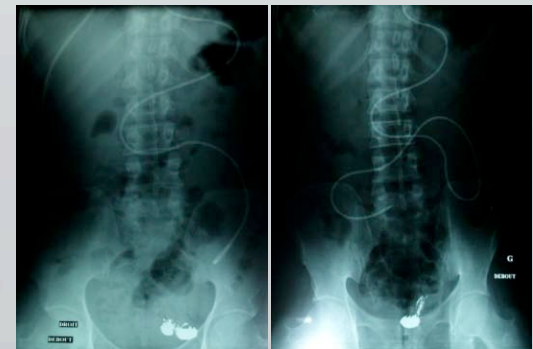
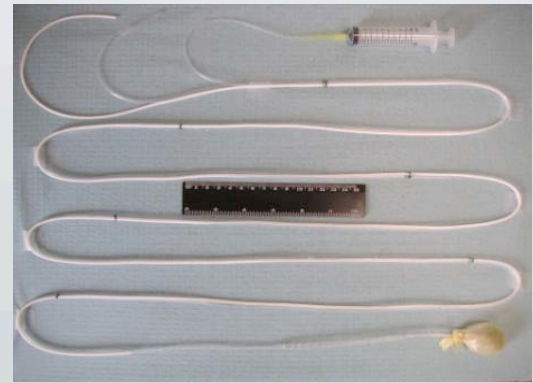
Subjects

- Healthy volunteers
- Written informed consent is obtained
- Hospitalization

Gastro-intestinal perfusion

- A PVC triple-lumen tube is inserted via the nose under local anesthesia
- The tube is swallowed so as to progress down the gastrointestinal tract
- Verification is performed under X-ray
- The tip is halted in the desired intestinal fragment
- Intestinal fluids and blood are sampled at regular intervals over a determined time period

Bioanalysis and determination of PK parameters



Timelines

From protocol design to results

- Study starts after protocol design ratification by the Sponsor
- Ethical committee and AFSSAPS acceptance: 4 months
- Recruitment of healthy volunteers : 2 to 4 months
- Study at the Hospital and documentation: 2 months
- Bioanalysis and report at Oroxcell: 1 month
- Overall report is provided

Avicenne hospital: Gastro-enterology group

Leaded by Pr Robert BENAMOUZIG

- Gastro-enterologist
- Clinician
- Nutritionist

Group expertise

- Digestive endoscopy
- Gastro-enterology
- Hepato-gastro-enterology
- Genetics
- Proctology

Beds

- Beds: 28
- Beds dedicated to *in situ* gastro-intestinal perfusion studies: 4



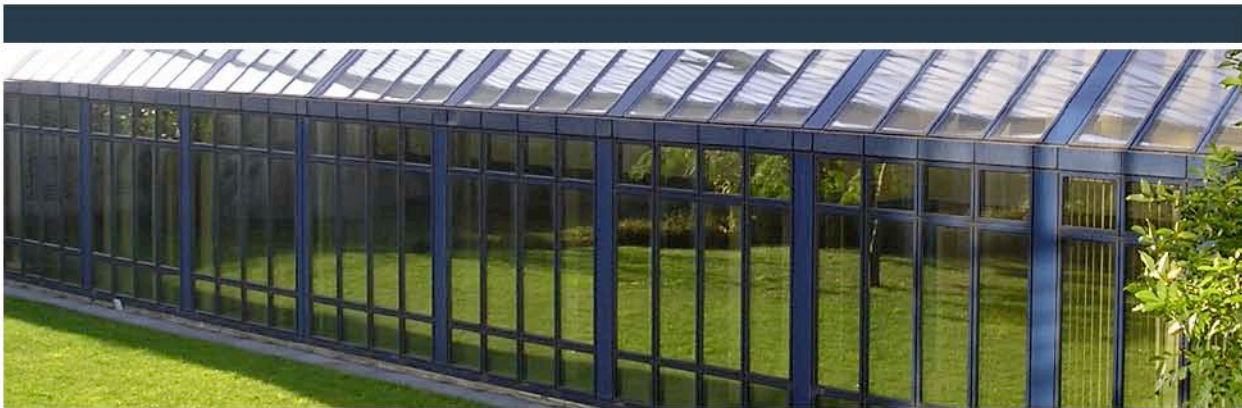
Avicenne hospital

Member of AP-HP, Paris Public Hospitals



Internationally recognized expertise in different therapeutic areas

Emergency-Anesthesia-Resuscitation, Bacteriology-Virology-Parasitology-Tropical Diseases, Gastro Enterology, Digestive Surgery, Oncology-Nuclear Medicine, Pain & Palliative Care, Endocrinology - Diabetes & Metabolic Diseases, Cardiovascular-Thoracic & Vascular Surgery, Clinical Hematology, Dermatology, Neurology & Neurological Rehabilitation, Psychopathology of Children & Adolescents, Psychiatry & Addiction, Pneumology, Rheumatology, Orthopedic Surgery, Ophthalmology, Pharmacology, Toxicology, Radiology.



Oroxcell SAS

Parc Biocitech
102, avenue Gaston Roussel
F-93 230 Romainville

Tel: 00 33 (0) 1 41 83 72 20
Fax: 00 33 (0) 1 41 83 72 27
E-mail: contact@oroxcell.com

www.oroxcell.com