Research Networking Programmes

Science Meeting – Scientific Report

The scientific report (WORD or PDF file - maximum of seven A4 pages) should be submitted online within two months of the event. It will be published on the ESF website.

***Proposal Title*: Minutes of the CHIRACIC meeting**

***Application Reference N°*: Science Meeting 5633**

1) **Summary (up to one page)**

2) **Description of the scientific content of and discussions at the event (up to four pages)**

3) **Assessment of the results and impact of the event on the future directions of the field (up to two pages)**

4) **Annexes 4a) and 4b): Programme of the meeting and full list of speakers and participants**

1) SUMMARY

It was the first CHIRACIC investigator meeting which took place in Paris, in the “Hôpital Européen Georges Pompidou”, 7rd floor, room A on Thursday, September 25th from 13:30 to 17:00.

It included following speakers:

- Pr Tabarin:
  - Introducing study team and all participant centres
  - Principal and secondary objectives
  - Eligibility criteria
  - Study flow-chart and all study visits design
  - Pre-selection visit scenario
  - Standardized Antihypertensive Regimen
  - Randomization

- Dr Amar:
  - OMRON use and 24H ambulatory blood pressure measurement recording guidelines
  - Antihypertensive treatments management
  - Required attitude for post-surgical hypotension

- Dr Perez and C. Maldonado:
  - Electronic case report form

- S. Cazenave:
  - Financial and administrative management (amounts and supplied devices, hospital agreements and financial agreements organization)
  - Serious adverse events management
  - Centralized laboratory management

2) DESCRIPTION OF THE SCIENTIFIC CONTENT OF AND DISCUSSIONS AT THE EVENT

A. Description of the scientific content

A.1. Study presentation

We began the meeting introducing the study team and all participant centres (1 coordinating centre, 15 French centres, 3 German centres and 6 Italian centres).

Then, we presented principal and secondary objectives and a protocol overwiew.
We insisted on three key points to ensure a good progress of the study: the tumor, endocrine biology and presence of hypertension.

We explained in details eligibility criteria, insisting on unilateral incidentaloma, biochemical criteria of Subclinical Cortisol-Secreting adrenal Incidentaloma (SCSI) and systolic and diastolic blood pressure > 135/85 mmHg. We explained it is necessary to assess again eligibility criteria after Run-In phase.

We detailed study flow-chart and all study visits.

- There are three pre-selection visit scenarios:
  - New patient with recently discovered adrenal incidentaloma and treated hypertension
  - New patient with recently discovered adrenal incidentaloma but no history of hypertension and no anti-hypertensive treatment
  - Patient followed for already diagnosed SCSI

  It is important to follow all the steps of the good pre-selection visit scenario.

- On the screening visit, we insisted on keeping attention to Standardized Antihypertensive Regimen (SAHR) concepts and steps.

- During the Run-In period (one visit each month, between 2 or 5 months), we have to set up the SAHR adaptation.
  At the End of Run-In visit (≤ 1 month after last visit) we have to check again all inclusion and exclusion criteria to ensure patient is eligible.

- Randomization occurs before one month after End of Run-In visit. There are two possibilities: surgery for Intervention group (≤ 1month after Randomization visit) and Control group.

- Follow-up occurs until Randomization+13Months visit, with essential points to control:
  - Hydrocortisone substitution procedure and adaptation according to fasting cortisol and SST for operated patients
  - Corticotropic evaluation for operated patients with patent or latent cortisol insufficiency
  - SAHR modification on each visit with a first attempt to decrease SAHR on Randomization+2.5Months visit and a second attempt to decrease SAHR on Randomization+8.5Months

A.2. OMRON guidelines, antihypertensive treatments and adverse events management

We explained the OMRON use for blood pressure self measurement and 24H ambulatory blood pressure measurement recording guidelines.

We also detailed antihypertensive treatments and the required attitude for post-surgical hypotension.

A.3. eCRF presentation

We explained how to log on, use extra documents, fill in the study electronic case report form and randomize patients.

A.4. Financial and administrative management – SAE management – Centralised biological samples

We detailed financial and administrative study management.
For all centres:

- A total of 3 360 € per patient who complete the all study are available
- 2 supplementary consultations in the non operated group are financed (25€)
- Supplementary DEXA (both patient groups) and CT-Scan (operated patient group) are financed (39.96 € and 132.94 €)
- 2 € for each CD of DEXA and CT-Scan performed are financed
- Salivettes for late night salivary cortisol are supplied
- Shipments of frozen centralized samples are organized and financed
- The OMRON advice (blood pressure self measurement) is supplied and shipment financed (with a CD and information brochure)

Then we gave important information about:

- Hospital agreements organization for French centres and financial agreements organization for foreign centres
- Meeting travel reimbursement

We concluded with serious adverse event management (procedures, vigilance unity fax and telephone number) and centralised laboratory samples management (samples have to be stored in each centre and shipped to Bordeaux every year).

B. Discussions at the event

There was a specific discussion with Dr Amar about possible hypotension episodes. When there is suspicion of hypotension, it is necessary to anticipate BP self measurement during 5 days and ask patient to communicate results.
When there is a proven hypotension (SBP<100mmHg and/or DBP<60 mmHg), an anticipated consultation is necessary with control of BP self measurement data, decrease SAHR to previous step and no modification of the next visit schedule.
When hypotension event is managed by another practitioner, it is important to follow expected visits calendar and indicate in eCRF the crucial information: therapeutic modifications performed and current SAHR step, lowest SBP and lowest DBP, BP self measurement data.

The case of malignant hypertension (> 175/115 mmHg) was discussed and considered as exclusion criteria.

Pr Beuschlein discussed about the identification code of patient and labelling of plasma/saliva/urine samples according to the ENS@T process.

The regulatory rules about conventions between Bordeaux Hospital and foreign centres were discussed.

Pr Beuschlein and Pr Fassnacht proposed modifications of the eCRF that were took in consideration.

Dr Assie raised the problem of renal insufficiency that hampers accurate UFC measurement. Chronic renal insufficiency will be added as exclusion criteria.

Representative of Italian centres tackled about salivettes to collect salivary cortisol: Bordeaux Hospital will provide a specific brand of salivettes.

3) ASSESSMENT OF THE RESULTS AND IMPACT OF THE EVENT ON THE FUTURE DIRECTIONS OF THE FIELD

Impacts of this meeting are the following points:

- Better understanding of the protocol and patient care by investigators
- Modification of the protocol with regard to:
  - malignant hypertension
  - identification code of patient and labelling of plasma/saliva/urine samples according to the ENS@T process
  - chronic renal insufficiency patients
- Modification of the eCRF
- Raised the issues of convention between Bordeaux Hospital and foreign centres
- Allow the beginning of the study by January 2015.

4) ANNEXES

Annex 4a): Programme of the meeting

CHIRACIC INVESTIGATOR MEETING - Thursday, September 25th

13h30: Study presentation – A. TABARIN
14h30: eCRF presentation – P. PEREZ, C. MALDONADO
15h00: Financial and administrative management – S. CAZENAVE
15h30: OMRON guidelines – L. AMAR
16h10: Antihypertensive treatments and adverse events management – L. AMAR
16h40: Serious adverse events management – S. CAZENAVE
16h50: Centralised biological samples – S. CAZENAVE

Annex 4b): Full list of speakers and participants

Speakers

NAME	AFFILIATION	CITY	COUNTRY
Dr Laurence AMAR	APHP hospital	PARIS	FRANCE
Sarah CAZENAVE	University hospital	BORDEAUX	FRANCE
Catherine MALDONADO	USMR	BORDEAUX	FRANCE
Dr Paul PEREZ	USMR	BORDEAUX	FRANCE
Pr Antoine TABARIN	University hospital	BORDEAUX	FRANCE

Participants

NAME	AFFILIATION	CITY	COUNTRY
Pr Giorgio ARNALDI	University private hospital	ANCONA	ITALY
Pr Guillaume ASSIE	APHP hospital	PARIS	FRANCE
Pr Felix BEUSCHLEIN	University private hospital	MUNCHEN	GERMANY
Dr Margaux BLADZIAK	University hospital	ROUEN	FRANCE
Pr Philippe CARON	University hospital	TOULOUSE	FRANCE
Dr Elena CASADIO	Hospital	BOLOGNA	ITALY
Dr Filipo CECCATO	University hospital	PADOVA	ITALY
Dr Brigitte DELEMER	University hospital	REIMS	FRANCE
Dr Delphine DRUI	CIC	NANTES	FRANCE
Pr Martin FASSNACHT-CAPELLER	University hospital	WUERZBURG	GERMANY
Pr Natacha GERMAIN-ZITO	University hospital	SAINT-ETIENNE	FRANCE
Dr Tina KIENITZ	University hospital	BERLIN	GERMANY
Dr Sandrine LABOUREAU-SOARES	University hospital	ANGERS	FRANCE
Dr Florina LUCA	University hospital	STRASBOURG	FRANCE
Dr Serena PALMIERI	University hospital	MILANO	ITALY
Pr Pierre-François PLOUIN	APHP hospital	PARIS	FRANCE
Pr Yves REZNIK	University hospital	CAEN	FRANCE
D. Mona SAHNOUN-FATHALLAH	APHM hospital	MARSEILLE	FRANCE
Dr Antonio SALCUNI	Hospital	SAN GIOVANNI ROTONDO	ITALY
Pr Marie-Christine VANTYGHEM	University hospital	LILLE	FRANCE
Pr Georges WERHYA	University hospital	VANDOEUVRE	FRANCE
Pr Jacques YOUNG	APHP hospital	LE KREMLIN BICETRE	FRANCE
Dr Valentina ZHYGALINA	APHP hospital	PARIS	FRANCE