CP10
THE EFFECTS OF TREATMENT ON DISEASE SYMPTOMS AND PROGRESSION OF STRUCTURAL CHANGES IN KNEE OSTEOARTHRITIS PARTICIPANTS FROM THE OSTEOARTHRITIS INITIATIVE PROGRESSION COHORT

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Objective: To evaluate the role of meniscal extrusion on the effects of conventional Osteoarthritis (OA) pharmacological treatment and those of glucosamine and chondroitin sulfate (Glu/CS) on knee structural changes, using data from the progression cohort of the OA Initiative (OAI). The OAI allows to study the potential disease-modifying OA drug (DMOAD) effects in patients over time following the evolution of OA structural changes over time and the associated risk factors.
Method: Participants (n = 600) were selected from the Osteoarthritis Initiative (OAI) progression cohort (http://www.oai.ucsf.edu/) (n = 1,390) who met the following criteria: 24 consecutive months of follow-up with clinical and imaging data including radiographs and magnetic resonance imaging (MRI) of the target (highest WOMAC pain) knee. Data for joint space width (JSW) were obtained from the OAI database and cartilage volume was measured using a fully-automated MRI.
Results: Participants reported taking (+) (n = 300) or not taking (-) (n = 300) OA treatment (analgesic/NSAID, etc.) over 24 months, with or without glucosamine and chondroitin sulfate (Glu/CS). The +analgesic/NSAID subjects had higher WOMAC scores ($P < 0.0001$) and smaller JSW ($P = 0.013$) reflecting more severe disease at the onset of the study (T0). In the analgesic/NSAID group, subjects taking Glu/CS had a smaller loss of JSW at 12 months ($P = 0.057$) and cartilage volume at 24 months in the medial central tibial plateau ($P = 0.022$ univariate and $P = 0.025$ multivariate analysis). In the +analgesic/NSAID group, those taking Glu/CS had significantly lower WOMAC scores (pain, $P < 0.0001$; stiffness, $P = 0.037$; disability, $P = 0.0004$) and higher KOOS scores at T0 as well as a smaller cartilage volume loss in the tibial plateau at both 12 ($P = 0.029$) and 24 months ($P = 0.033$).
Conclusions: In both the + and − analgesic/NSAID groups, participants who took Glu/CS had reduced loss of JSW and cartilage volume over 24 months. These effects of Glu/CS on structural changes support results from previous studies.

CP11
A COLLABORATION BETWEEN PRIMARY CARE AND THE RAMON Y CAJAL HOSPITAL. THE VALUE OF SCREN (SPANISH CLINICAL RESEARCH NETWORK) TO SUPPORT AN INDEPENDENT MULTICENTER CLINICAL TRIAL WITH MEDICAL PRODUCTS

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Objective: A multicenter independent clinical trial (CT) with medicinal products needs a strong infrastructure to ensure its feasibility. It is essential to carry out these studies in Primary Care (PC). We analyze the problems emerged during the set up of the first independent multicenter CT with medical products in PC in the Autonomous Community of Madrid.
Method: This is a pragmatic, controlled, randomised, multicenter, parallel, non-inferiority CT to compare the effectiveness of orally and intramuscularly administered vitamin B12 in the treatment of patients ≥65 years-old with vitamin B12 deficiency. The study obtained public funding for study drugs, insurance and eCRD. The prevalence of the disease is 10%. It is estimated to screen 3000 patients to randomize 300 of them. To achieve this, 23 PC sites were incorporated into the study, including around 191 investigators participating. The study is supported by the PC clinical research unit that provides methodological and logistical support. Nevertheless, the complexity of the trial made necessary to be additionally supported by by a public consortium (CAIBER) for regulatory submissions, project management, clinical monitoring and pharmacovigilance activities.
Results: The beginning of the trial has been delayed due to several issues. One of them was the dissolution of CAIBER, which made necessary to get additional supports. The first one was to implement a pharmacovigilance agreement with the Clinical Trial Unit (UICEC) of the Ramon y Cajal Hospital in 2012. The second one was to include the CT in SCReN in 2014 to ensure compliance with ethical, clinical monitoring and regulatory requirements. Other problems and difficulties (political and economic) are discussed.
Conclusions: To implement and conduct a multicenter CT in PC is necessary to have a strong structure to support clinical research. The CT presented here is an example of collaboration between Primary Care and Medical Hospital supported by SCReN.

CP12
ASSESSMENT OF THE LEVEL OF UNDERSTANDING OF INFORMED CONSENT (IC) FROM THE PATIENTS PARTICIPATING IN CLINICAL TRIALS (CT)

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Objective: To document the degree of understanding of the IC from the patients participating in CT. To know the patients reasons for participating in CT, and to assess the degree of patient satisfaction with Clinical Trials Unit (CTU).
Method: A survey was provided to patients admitted to the CTU during May-June 2014. All of them participated in CT that were coordinated by others services. The survey was approved by the Hospital's Ethical Committee and reviewed by all the principal investigators of each CT.
Results: Twenty-four patients fulfilled the survey. All respondents were in possession of the IC who had read and signed, and 92.3% answered they understood correctly what it means to participate in a CT. All understood that their participation in the study was voluntary, however two patients believed that they couldn't withdraw the study when they wanted. 21 patients consulted the decision of participating with their families before signing the IC and less than half of the respondents signed the IC in their next visit to the centre. The most frequent reason for participating in the study was confidence in the physician.
All respondents thought that the treatment received by the CTU's staff and the facilities were good/very good. Six patients responded that the arrival of medication from the pharmacy needed to be expedited. Two patients felt they had more trouble than expected.
Conclusions: Most of the respondents understand what it means to participate in a CT. It's desirable that patients have adequate time to assess their participation in the study but we did not observe it. The most frequent reason for participating in the study was confidence in the physician and most of the respondents consulted with their families before making a decision. Treatment received in the CTU was classified as very good/good.