-0.55 points, respectively; group difference, 0.89 points; 95%CI -3.89 to 5.68; $p=0.713$). Week 52 least squares means for body weight and KOOS pain showed similar results (Figure 2). 4 patients in the intervention and 4 patients in the control groups experienced serious adverse events, and no deaths were observed.

Conclusion: In overweight patients with knee OA, an 8-week low-calorie diet intervention significantly reduced body weight and knee pain. Liraglutide treatment added after the initial diet-induced weight loss provided further weight loss over 1 year but did not reduce knee pain any further compared to placebo.

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WEDNESDAY, 12 JUNE 2019

What's new: Latest news on biological treatment

OP0012

EFFECTIVENESS OF TNFI AFTER A FIRST SWITCH IS LOWER IN PATIENTS WITH EARLY AXIAL SPONDYLOARTHRITIS: A LONGITUDINAL ANALYSIS OF THE DESIR COHORT

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Background: Some contradictory data has been reported on the effectiveness of a second and third line of TNFi in early axial spondyloarthritis (axSpA).

Objectives: To evaluate the effectiveness after a first and second TNFi switch, in real life conditions, over 5 years of follow-up in an early axSpA population.

Methods: Observational prospective French cohort (DESIR) with 5 years of follow-up, including 708 TNFi-naïve early axSpA patients. Study visits were scheduled every 6 months in the first two years of follow up then yearly up to 5 years. Treatment (TNFi or other) was at the discretion of the treating rheumatologist's. The characteristics of patients who received a second and a third TNFi were compared to those who never switched. Effectiveness was defined by the drug survival of the first, second and third TNFi were estimated by the Kaplan-Meier method, and compared using the log-rank test.

Results: Of the 708 patients included in the analysis, 258 (36.4%) patients initiated a first TNFi during the 5 years of follow up. Of these, 127/258 (49.2%) switched to a second TNFi, and among them 59/127(46.5%) switched to a third TNFi. Patients who switched to a second or a third TNFi were more frequently older, predominantly females, HLA-B27 negative, with MRI and radiographic sacroiliitis negative, without history of peripheral arthritis, and with higher BASFI and BASDAI scores at baseline of the DESIR cohort (see table). Estimated median drug survival for the first, second and third TNFi was 21.7 months [95%CI 17.6-33.6], 18.8 months [95%CI 15.1-24.4] and 25.0 months [95%CI 11.8-NA] respectively. Drug survival was significantly extended for the first TNFi compared to the

second one ($p=0.04$), but no differences were observed between the 2nd and the 3rd TNFi.

Conclusion: Our study suggests a poorer TNFi effectiveness after a first switch in real-life conditions in early axial spondyloarthritis.

Baseline characteristics	Patients remaining in their first TNFi N=88	Patients switching to a 2 nd TNFi N=127	Patients switching to a 3 rd TNFi N=59
Age (years)	33.6(9.4)	35.3(8.7)	35.4(8.5)
Sex (male)	52(59.1)	40(31.5)	17(28.8)
HLA-B27 positive	57(64.8)	62(48.8)	26(44.1)
MRI sacroiliitis positive	46/85(55.1)	39/125(31.2)	16/57(28.1)
Radiographic sacroiliitis positive	27/85(31.8)	17(13.4)	9(15.3)
History of arthritis	31(35.2)	37/125(29.6)	17/58(29.3)
BASDAI (range 0-10)	4.5(1.8)	5.9(1.5)	6.0(1.4)
BASFI (range 0-10)	3.1(2.1)	4.6(2.1)	4.8(2.1)

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OP0013-PARE AFLAR'S – FRENCH LEAGUE AGAINST RHEUMATISM –POSITION AND PATIENT INFORMATION ACTION ABOUT BIOSIMILAR MEDICINES IN FRANCE

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Background: 20 years after biotherapies were introduced in rheumatic diseases treatment in France, biosimilars are a new medical and economic issue in terms of therapeutic opportunities, and innovative treatment spreading and development. Patients' rights - quality of life, information on treatment and safety - as well as public health cost management, medical and other caregivers' practices are involved.

Objectives: AFLAR wants to play an active role in these fields, as about one million of patients with inflammatory rheumatic diseases, and next other diseases, are concerned.

Methods: AFLAR's patient led board (1), medical and scientific experts and especially expert patients have been working together to:

1. state AFLAR's position about biosimilars
2. define the most adapted association's actions in the field of biosimilars
3. create the most proper tool to inform and empower patients to their rights, especially in the field of treatment efficacy and safety.

Results: A position paper leading to a press release dated Dec. 7th, 2018 prior to national rheumatology medical congress opening has been achieved. An informative tool to be used for shared medical decision when biosimilars are involved, is currently in progress. AFLAR'S position on biosimilars includes 2 statements and 6 advices addressed to patients, caregivers and other stakeholders:

Statements:

1. Biosimilars are a medical and healthcare cost reduction effective solution in rheumatic diseases treatment;
2. Biosimilars have scientifically proved their efficacy and safety in past and ongoing studies; drug safety monitoring is ensured by national and European drug safety agencies.

Advices:

1. Further continuous clinical post-marketing studies should be achieved, and their results easily available to patients.
2. Patient should be properly informed each time a biosimilar is proposed if has not been tested versus original biotherapy in his/her own specific disease
3. Biosimilar drug can be prescribed for cost reduction reason as initial biotherapy treatment, when not contraindicated
4. Blind random switch from originator to biosimilar and among biosimilar products should not be done, based on precautionary principle
5. Patient should be precisely informed of product with biosimilar name (not only international non-proprietary name), and batch number, as this allows

mandatory pharmacovigilance by professionals and patients. As per law (2) and professional ethics, patient preference and right to informed consent must prevail.

- Self-assessment surveys, and patient reported outcomes using studies, should be encouraged. These are facilitated by new information technologies practices and devices.

Conclusion: The information tool will be proposed in the form of an information letter to be remitted by professionals to patient when biosimilar prescription or initiation is planned. The process includes:

- creation of document by expert patients
- user testing of tool (assessment about understandability and usefulness), in hospital departments, patient groups and on-line
- knowledge assessment and opinion gathering among patients about biosimilars.

REFERENCES:

- According to its current by-laws, AFLAR board consists of at least 2/3 of persons affected with/concerned by rheumatic diseases, and/or presidents of affiliated patient associations.
- Articles L1111-2 and L2002-303 Code de Santé Publique

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How to perform low-budget high-quality research

OP0014

NO ASSOCIATION BETWEEN THE PROPORTION OF ELDERLY PEOPLE AND TRIAL RETENTION IN RHEUMATOID ARTHRITIS AND OSTEOARTHRITIS TRIALS: A SYSTEMATIC REVIEW WITH META-REGRESSION ANALYSES

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Background: The elderly (defined by an age of ≥ 65 years) are underrepresented in current rheumatoid arthritis (RA) and osteoarthritis (OA) trials.¹ This is partly due to age-related exclusion criteria. Investigators might be reluctant to include more elderly people because they fear reduced trial retention.

Objectives: To evaluate whether the proportion of included elderly individuals (PE) is associated with trial retention in current RA and OA trials.

Methods: This study is registered with protocols.io (dx.doi.org/10.17504/protocols.io.uhaet2e). In our previous study,¹ two systematic searches in MEDLINE had yielded randomized controlled trials (RCTs) in rheumatoid arthritis (RA) and osteoarthritis (OA) on any intervention published in 2016 and 2017. Here we included all trials reporting data on retention. We either extracted the PE from the research manuscript or estimated it from an assumed (truncated) normal distribution. We coded retention into proportional effect sizes (logit-transformed for analysis and back-transformed for reporting). Subsequently, multiple mixed effects meta-regression models with several covariates assessed whether there is an association between the PE and trial retention. Sensitivity analyses evaluated whether associations were connected to attrition due to lack of efficacy (LoE) or adverse events (AE).

Results: 243 RCTs comprising 48,288 participants were deemed eligible, and 227 RCTs provided complete data on overall retention and all covariates. Pooled trial retention (random effects) was 88% (95%-CI 87% to 90%; $I^2 = 90\%$). The PE was not associated with trial retention in the unadjusted (slope $\beta = 0.0$ [-0.0 to 0.0]; $p = 0.97$; **Figure 1**), or any protocolized adjusted model (p -values depending on the adjustment: 0.14 to 0.90). Of all included covariates, only study duration (longer study duration being associated with inferior retention: $p < 0.001$) and the type of intervention (surgical interventions averaging the highest retention; psychological interventions averaging the lowest retention: $p < 0.001$) were associated with trial retention. Post hoc analyses allowing for interaction revealed a small statistically significant association between the PE and trial retention in pharmacological (retention increasing with the PE) and physical/physiotherapeutic (retention decreasing with the PE) interventions. Further sensitivity analyses showed no significant associations between attrition due to LoE or AE and the PE in any model.

Conclusion: Trial retention in RA and OA trials is very high, and unaffected by the proportion of elderly.

Figure 1. Bubble plot of trial retention against the proportion of elderly people. The size of each bubble is inversely proportional to the standard error.

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