Classification of Axial SpondyloarthritiS Inception Cohort

Protocol Summary

Primary Objective:

To test ("validate") the performance of the current ASAS classification criteria in a prospective cohort of patients presenting to a rheumatologist in North America with undiagnosed current back pain of ≥3 months duration with onset ≤45 years of age.

Primary Endpoint:

Classification criteria that attain specificity of ≥90% and sensitivity of ≥75%

Investigational Plan Overview:

- All consecutive patients referred to a rheumatologist with undiagnosed current back pain of ≥3 months duration with onset ≤45 years of age will comprise the prospective cohort.
- Sample size = **500**
- All patients will have a full clinical assessment, followed by lab tests (CRP & HLA-B27), a pelvic radiograph and a pelvic MRI.
- Rheumatologist will complete 5 Diagnostic and Confidence Assessments to determine the presence/absence of axSpA
- The study will flow through 5 phases, and must be completed in the order outlined:

Location	Type of Information provided	PHASE:				
		1	2	3	4	5
Central Site Experts	Plain X-ray images interpreted					X
	MRI interpreted					X
Local Investigator	Clinical information	X				
	Serologic data (HLA B27, CRP)		X			
	Plain X-ray images interpreted			X		
	MRI results images interpreted				X	
	Diagnostic & Confidence Assessment	X	X	X	X	X

- The **Diagnostic & Confidence Assessment** occurs after all the data are gathered in each phase (e.g. in phase 2, the Diagnostic & Confidence Assessment occurs after the local investigator becomes aware of the HLA B27 and CRP results).
- Imaging interpretation in **phase 4** will be performed by the local investigator and a designated radiologist. Imaging interpretation in **phase 5** will be a "shared interpretation" performed jointly with local investigator and central site experts, with the purpose of serving an educational function.
- Patient contact information will be obtained for a potential 5 year follow up

Study Procedures:

1) Study coordinators will use a patient eligibility checklist to screen for potential study participants:

2)

1. Do/Did you have any back, buttocks or hips discomfort in the last week?

   Yes □ No □

   If Yes, continue to question 2 and 3. If no discomfort in the last week, cannot consider current and therefore patient is not eligible.

2. Have you had discomfort in your back, buttocks, or hips that has lasted **at least three months**?

   Yes □ No □

3. If yes, did your first symptoms of pain begin when you were less than or equal to 45 years of age:

   Yes □ No □

Important Notes:

- Patients must answer "YES" to questions 1, 2 and 3 in order to be eligible.
- Eligibility requires back or buttock pain - some patients refer to this pain as "hip" pain, so it is critical to assess the area of the patient's pain appropriately.
- Patients with a prior rheumatologist confirmed diagnosis of SpA at the time of referral to the PI will NOT be considered eligible.

3) Study coordinator will remove any information that should not be visible to the PI at the time of the first global evaluation: X-ray and MRI reports, lab results, etc.

4) Study coordinator will notify the PI that the patient is eligible for the study and provide them the completed patient eligibility checklist and the censored patient file.

5) The PI will verify patient eligibility, conduct the initial clinical assessment, followed by the first global assessment.

6) Study coordinator will ensure that the following procedures are scheduled after the initial clinic assessment:

Lab Assessments	Pelvic X-ray	Pelvic MRI
CRP & HLA B-27	Standard AP view of the pelvis must be ordered, if not done in the last **6 months**	MRI of the SI joints to be ordered and the requisition must be sent with: • The 'Radiologist Global Evaluation Form' • The axial SpA-specific imaging guidelines

7) As the required information for each assessment phase (1-5) is obtained, the local rheumatologist will complete each of the diagnostic and confidence assessments:

1st Global Assessment	**After the clinical assessments, at the end of the patient encounter**
2nd Global Assessment	**After lab results are available (CRP & HLA-B27)**
3rd Global Assessment	**After the pelvic radiograph has been reviewed by the rheumatologist**
4th Global Assessment	**After the rheumatologist has reviewed the report of the pelvic MRI scan provided by the local designated radiologist.**
5th Global Assessment	**After central review of the anonymized radiograph and pelvic MRI scan and feedback to both the rheumatologist and radiologist**

8) Once all assessments are complete, the patient will be followed according to the discretion of the rheumatologist and appropriate standards of clinical practice.

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