PATHOBIOLOGY OF EARLY ARTHRITIS COHORT

STUDY NUMBER	PATIENT INITIALS	VISIT	SITE	DATE

SCREENING AND RECRUITMENT

STUDY SPECIFIC CONSENT OBTAINED	DATE	TIME

1. INCLUSION / EXCLUSION CRITERIA

Please Tick appropriate response

INCLUSION CRITERIA	YES	NO
1. Arthritis symptoms for less than 1 year		
2. One or more swollen joint		
3. Disease activity score (DAS 28) > 2.6		
4. Over 18 years of Age		

EXCLUSION CRITERIA	YES	NO
1. Patient in whom a synovial biopsy is contra-indicated (e.g. receiving anti-coagulant medication / unsuitable joint)		
2. Patient with severe concomitant medical problem (e.g. end stage renal disease) **This decision is left to the physicians' discretion**		
3. Under 18 years of Age		

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2. DEMOGRAPHICS

HOSPITAL NUMBER	
GENDER	
DATE OF BIRTH	
AGE	
ETHNICITY	
MARITIAL STATUS	
OCCUPATION	
EDUCATION	

3. MEDICAL HISTORY

MEDICAL CONDITIONS	YEAR OF DIAGNOSIS	ACTIVE	
		YES	NO

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4. FAMILY HISTORY OF RHEUMATIC DISEASE

NO ❑ YES ❑ if YES please specify below

RELATIVE	RHEUMATIC CONDITION

5. CONCOMITANT MEDICATION

NOTE: Please record all current medication

DRUG NAME	DOSAGE (UNITS) / UNIT TIME e.g. 15 mg / DAY	START DATE		CONDITION BEING TREATED

NOTE: Synovial Biopsy ideally should not be performed within 1 month of steroid therapy

RECENT STEROID THERAPY?	PLEASE TICK		DATE COMMENCED	NAME + DOSE e.g Prednisolone 7.5mg o.d.	CONDITION BEING TREATED
	YES				
	NO				

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6. CARDIOVASCULAR RISK FACTORS

Please Tick appropriate response

			YES	NO
Smoking history				
If **NO** then is the patient a previous smoker				
If **YES** please give number of pack years (smoking years **x** packs/day)				
Alcohol Consumption (units / week)				
Previous CV events (please document with medical history)				
Family history of CV events				
Relative		Event		
Relative		Event		
Relative		Event		

7. VITAL SIGNS

MEASUREMENTS	RESULTS
WEIGHT (KG)	
HEIGHT (M)	
BMI (KG/M^2)	
BLOOD PRESSURE: SYSTOLIC / DIASTOLIC mmHg	
PULSE	

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8. ACR CRITERIA

Please Tick appropriate response

	YES		NO
Symmetrical Arthritis > 6 weeks			
Arthritis involving hands > 6 weeks			
3 joint areas affected > 6 weeks			
Subcutaneous nodules			
Early morning stiffness > 1 hour > 6 weeks			
X-ray evidence of Rheumatoid Arthritis			
Rheumatoid Factor If **YES** please give titre value		Titre	

9. VISSER'S POGNOSTIC FEATURES

Please Tick appropriate response

	YES		NO	POINTS	PATIENTS SCORE
MTP Squeeze				1	
Arthritis ≥ 3 joint groups				1	
Length of symptoms prior to presentation (weeks)					
Symptoms < 6 months				2	
Symptoms > 6 months <1 year				3	
Morning stiffness > 1 hour				1	
Anti-CCP Positive If YES please give titre		Titre		3	
Rheumatoid factor Positive If YES please give titre		Titre		2	
X-ray evidence of erosions				2	
TOTAL SCORE					

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10. DIAGNOSIS

Please Tick appropriate response

Please tick the appropriate diagnosis	PSORIATIC ARTHTIS	RHEUMATOID ARTHRITIS*		UNDIFFERENTIATED ARTHRITIS**		MONO-ARTHRITIS
PROGNOSIS		GOOD	BAD	GOOD	BAD	

**Rheumatoid arthritis* - Bad prognosis will be inferred if there is the presence of (i) DAS-28 over 5.1; (ii) seropositivity for rheumatoid factor or anti-CCP; (iii) one or more radiographic erosions in the hands and feet. Other wise the patient will be assumed to have a good prognosis

***Undifferentiated Arthritis* - Bad prognosis will be inferred by the presence of anti-CCP antibodies or Vissers score > 6.

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11. JOINT ASSESSMENT

Please enter **1** or **0** or **N/A**

JOINT	LEFT	
	Painful	Swollen
IP		
PIP 2		
PIP 3		
PIP 4		
PIP 5		
MCP 1		
MCP 2		
MCP 3		
MCP 4		
MCP 5		
Wrist		
Elbow		
Shoulder		
Knee		
TOTAL		

JOINT	RIGHT	
	Painful	Swollen
IP		
PIP 2		
PIP 3		
PIP 4		
PIP 5		
MCP 1		
MCP 2		
MCP 3		
MCP 4		
MCP 5		
Wrist		
Elbow		
Shoulder		
Knee		
TOTAL		

ARE ANY JOINTS UNABLE TO BE ASSESSED?	**YES**	**NO**
IF YES PLEASE SPECIFIY		

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12.VISUAL ANALOGUE SCORES

1. Please rate how tired you feel today. Mark a line on the scale below at the point that best describes your level of tiredness.

NO TIREDNESS ⊢——————————————————⊣ EXTREMELY TIRED

SCORE ☐

2. How much pain are you suffering today? Mark a line on the scale below at the point that best describes your level of pain.

NO PAIN ⊢——————————————————⊣ SEVERE PAIN

SCORE ☐

3. Overall how active is your arthritis today? Mark a line on the scale below at the point that best describes how active your arthritis is today

NOT ACTIVE ⊢——————————————————⊣ EXTREMELY ACTIVE

SCORE ☐

4. Physicians Global Assessment

NOT ACTIVE ⊢——————————————————⊣ EXTEMELY ACTIVE

SCORE ☐

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13. DISEASE ACTIVITY SCORE

TENDER JOINT COUNT	
SWOLLEN JOINT COUNT	
ESR	
PATIENT VAS FOR GLOBAL HEALTH	
DAS 28 (ESR) Calculated by the formula: DAS28 = 0.56 √ (TEN28) + 0.28 √ (SW28) + 0.70 Ln (ESR) + 0.014 (GH)	

14. CHECK LIST AT END OF CONSULTATION

	DATE CONFIRMED	
	YES	**NO**
US ASSESSMENT (TIME 0 + EVERY 3 MONTHS)		
SYNOVIAL BIOPSY (TIME 0 + 6 MONTHS)		
X-RAYS Hands / Feet (TIME 0 + 12 MONTHS) Chest (TIME 0 ONLY)		
HAQ		
BLOODS FBC / U+E / LFTs / CRP / ESR / RF / CCP CHOLESTEROL / HDL / LDL / GLUCOSE		
TREATMENT COMMENCED **AS PER P.E.A.C. PROTOCOL**		
NEXT CLINIC VISIT		

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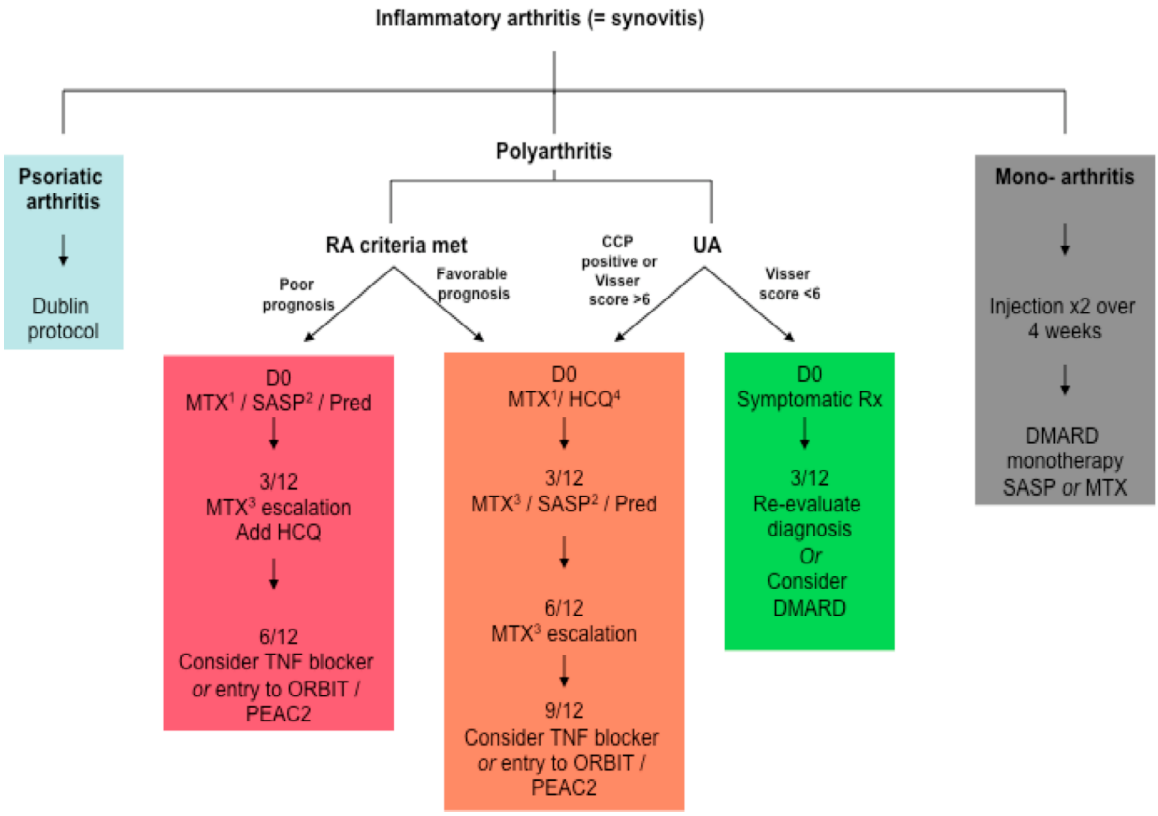
Therapeutic Algorithm



Footnotes to protocol

1. MTX dose commencement: Oral dose of 7.5mg per week together with 5 mg per week of folic acid. Escalate MTX by 2.5mg increments every two weeks as tolerated. This will achieve dose of 20mg per week by week 12 evaluation. Monitoring required per local practice. Non mandatory interim reviews may be necessary at the discretion of the treating rheumatologist.
2. SASP dose commencement: Oral sulphasalazine 500mg per day increased in 500mg increments weekly to target dose 2g per day or maximum dose tolerated. Monitoring required per local practice.
3. MTX further dose escalation: At week 12 assessment post MTX commencement, increase in 2.5mg increments every two weeks to target dose 25mg per week or as tolerated. Consider resort to parenteral MTX administration if no therapeutic response.
4. HCQ commencement: oral dose 200mg per day if patient <63kg and 400mg per day if >63kg, adjust higher dose down pending tolerance. Visual screening as per local practice.

Concomitant steroid rules

1. No steroid to a joint within 6 weeks pre-biopsy
2. 120-200mg depomedrone allowed at presentation and 6-8 weekly thereafter in appropriate prognostic groups
3. Oral prednisolone if used per protocol should be prescribed at 7.5mg p.o.
4. Intra-articular steroid injection allowed in addition - 10mg triamcinolone per small joint; 20mg triamcinolone to medium joint; 40mg triamcinolone to large joint. Dose equivalent steroid preparation may be used according to local practice.

Disease activity assessment

1. Should be evaluated 3 monthly through year 1
2. Therapeutic escalation performed every three months per protocol guidance. Escalation of therapy required if therapeutic failure since last evaluation. Defined as *either* DAS28 fall is <1.2 *or* DAS28 fall > 1.2 but residual DAS28 score is >3.2.