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# SUPPLEMENTARY MATERIAL

## The Italian Society for Rheumatology guidelines on reproductive health in patients with rheumatic diseases

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**Supplementary Table 1. Guidance for the appraisal of the quality of evidence and strength of the recommendations in accordance with the Grades of Recommendation Assessment, Development and Evaluation approach**.

| **Quality of Evidence** | | | |
|---|---|---|---|
| | **Expected impact on confidence of the estimate of the effect** | | |
| High | "Further research is very unlikely to change our confidence in the estimate of effect" | | |
| Moderate | "Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate" | | |
| Low | "Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate" | | |
| Very Low | "Any estimate of effect is very uncertain" | | |
| **Strength and Direction of a Recommendation** | | | |
| | **Patients** | **Clinicians** | **Policy makers** |
| **Strong in favor or against** | Most people in this situation would/would not want the recommended course of action and only a small proportion would not. | Most patients should/should not receive the recommended course of action. | The recommendation can/cannot be adapted as a policy in most situations. |
| **Conditional in favor or against** | The majority of people in this situation would/would not want the recommended course of action, but many would not. | Be prepared to help patients to make a decision that is/is not consistent with their own values. | There is/is not a need for substantial debate and involvement of stakeholders. |

**NOTE. For the following Tables the legend is as follows:**

Strongly recommend

Conditionally recommend

Conditionally recommend against

Strongly recommend against

**Supplementary Table 2. Recommendations for contraception in women with rheumatic diseases.**

| Topic and target population | Recommendation |
|---|---|
| Women with uncomplicated RD, other than SLE and without aPL positivity, if needed. | **1.1.a:** it is suggested to prefer the use of hormonal contraceptives or IUD over less effective contraceptive options or no contraceptive method. |
| | **1.1.b:** it is suggested to prefer the use of IUDs or progestin subcutaneous implants over other hormonal contraceptives. |
| Women with SLE and without aPL, if needed. | - In patients with stable disease (low disease activity),<br>**1.2.a:** it is suggested to prefer the use of progestin-only contraceptives, IUDs, or the vaginal ring over less effective contraceptive options or no contraceptive method. |
| | **1.2.b** it is suggested to prefer the use of IUDs and progestin implants over other hormonal contraceptive options. |
| | **1.2.c:** it is recommended to use combined estrogen-progestin pills or the vaginal ring, progestin-only contraceptives, or IUDs over less effective contraceptive options or no contraceptive method. |
| | - In patients with moderate to severe disease activity (including active lupus nephritis),<br>**1.2.d:** it is recommended to use progestin-only contraceptives (progestin-only pill, progestin implant) or IUDs and avoid the use of combined estrogen-progestin contraceptives. |
| Women with RD and positive aPL, if needed | **1.3.a**: it is recommended to avoid combined estrogen-progestin contraceptives. |
| | **1.3.b:** it is recommended to use IUDs (copper or progestin) or a progestin-only pill over other hormonal contraceptive options. |
| | **1.3.c:** in women with RD, including those with positive aPL antibodies, it is suggested to use emergency contraception (post-coital), if necessary. |
| Women with RD in special situations | **1.4.a:** in women receiving immunosuppressive therapy and desire an IUD, it is suggested the use of an IUD (copper or progestin) as an appropriate contraceptive. |
| | **1.4.b:** for reversible contraception in women taking mycophenolate mofetil or mycophenolic acid, it is suggested to use an IUD (alone) or the combined use of two alternative contraceptive methods. |

RD, rheumatic diseases; aPL, antiphospholipid antibodies; SLE, systemic lupus erythematosus; IUD, intrauterine device.

**Supplementary Table 3. Recommendations on assisted reproduction for women with rheumatic diseases.**

| Topic and target population | Recommendation |
|---|---|
| Women with uncomplicated RD | **2.1.a:** it is suggested to proceeding with ART when the disease is stable/quiescent and if aPL are negative. |
| Women with SLE and without aPL positivity, if necessary | **2.2.a**: it is recommended to postpone ART procedures in case of SLE or any other RD undergoing moderate-severe disease activity. |
| | **2.2.b**: in patients with SLE who undergo ART procedures, it is suggested to not introduce prophylactic doses of prednisone a priori (or increase the dosage for prophylactic purposes) for disease control. |
| Women with RD and positivity for aPL | **2.3.a:** in patients with stable/quiescent disease and positivity for aPL, it is suggested to undergo ART considering therapy with unfractionated or low molecular weight heparin as detailed below. |
| | **2.3.b:** Prophylactic anticoagulant therapy is suggested during ART procedures for patients with positive aPL who have not had clinical manifestations of APS. |
| | **2.3.c:** it is recommended to treat patients who have a history of obstetric APS, but not thrombotic APS, with anticoagulant therapy at least at prophylactic dose during ART procedures. |
| | **2.3.d:** it is recommended to treat patients with positivity for aPL who have a history of thrombotic APS with anticoagulant therapy at a therapeutic rather than prophylactic dose during ART procedures. |
| Women with RD in special situations | **2.4.a:** for the purpose of cryopreservation of oocytes or embryos, it is suggested to continue immunosuppressive and/or biological therapies (with the exception of cyclophosphamide) during ovarian stimulation and oocyte retrieval in patients with stable disease. |

RD, rheumatic diseases; ART, assisted reproductive technology; aPL, antiphospholipid antibodies; SLE, systemic lupus erythematosus; APS, antiphospholipid syndrome.

**Supplementary Table 4. Recommendations on pregnancy counseling for women with rheumatic diseases.**

| Topic and target population | Recommendation |
|---|---|
| Women with uncomplicated RD | **3.1.a:** in women with RD who are planning a pregnancy and are taking drugs incompatible with pregnancy, it is recommended to switch to a drug compatible with pregnancy and to proceed with an observation period to evaluate its effectiveness and tolerability. |
| | **3.1.b:** in case of active RD during pregnancy, it is recommended to start or continue a drug compatible with pregnancy. |
| | **3.1.c:** in women with RD who are considering pregnancy or are pregnant, it is recommended to test for anti-Ro/SSA and anti-La/SSB only once, preferably before or at the beginning of pregnancy. |
| | **3.1.d:** in women with RD who are considering pregnancy or are pregnant, it is recommended to perform antiphospholipid testing preferably before or at the beginning of pregnancy. |
| Women with RD and positive for anti-Ro/SSA and anti-La/SSB antibodies | **3.2.a:** it is suggested that patients be treated with HCQ during pregnancy. |
| | **3.2.b:** in the absence of a history of a newborn with congenital heart block or neonatal lupus (risk of complete heart block ~2%) it is suggested to perform a serial fetal echocardiography (with a frequency greater than a week although with an undetermined interval) starting from the 16th -18th week of gestation up to 26th week of gestation. |
| | **3.2.c:** in the presence of a history of a child born with congenital heart block or neonatal lupus (risk of complete heart block of 13-18%), it is suggested to perform a fetal echocardiography every week starting from the 16th-18th week of gestation until at the 26th week of gestation. |
| | **3.2.d:** in the presence of an abnormal fetal echocardiogram:<br>1. In case of 1st degree heart block, treatment with dexamethasone 4 mg orally per day is suggested<br>2. In case of 2nd degree heart block, treatment with dexamethasone 4 mg orally per day is suggested.<br>3. In case of isolated 3rd degree (complete) heart block (without other cardiac inflammation), it is suggested not to treat with dexamethasone. |
| Women with aPL positivity without APS | **3.3.a:** in women who do not meet the obstetric or thrombotic APS criteria, it is suggested not to treat the patient with HCQ prophylactically during pregnancy, if she does not need to perform HCQ therapy for other reasons. |
| | **3.3.b:** in women who do not meet the criteria for obstetric or thrombotic APS, it is suggested that the patient be treated with prophylactic LDA during pregnancy. |
| | **3.3.c:** in women who do not meet the criteria for obstetric or thrombotic APS and who do not have a high-risk profile, it is suggested not to treat with heparin prophylaxis or LMWH in combination with LDA. |
| Women with APS | **3.4.a:** in aPL-positive pregnant women who meet the criteria for obstetric APS and have no previous history of thrombotic events, |

| | |
|---|---|
| | the use of prophylactic doses of heparin (unfractionated or low molecular weight - LMWH) in combination with low-molecular-weight aspirin is recommended. |
| Women who meet the criteria for obstetric APS and have failed standard therapy with prophylactic dose heparin (unfractionated or LMWH) and LDA | **3.4.b:** In women who meet the criteria for obstetric APS and have failed standard therapy with prophylactic dose heparin (unfractionated or LMWH) and LDA:<br>**3.4.b.1:** it is suggested not to treat with IVIG in addition to prophylactic heparin and LDA.<br>**3.4.b.2:** it is suggested not to treat with prednisone in addition to heparin or LMWH in combination with LDA.<br>**3.4.b.3:** it is suggested to treat with therapeutic doses of heparin or LMWH in association with LDA only if not contraindicated. |
| | **3.4.c:** In women who meet the criteria for obstetric APS, the use of prophylactic heparin (unfractionated or LMWH) during the postpartum period is strongly recommended. |
| | **3.4.d:** in pregnant women with thrombotic APS, it is strongly recommended to treat with therapeutic dose of heparin in combination with LDA rather than using non-heparin anticoagulation. |
| | **3.4.e:** in pregnant women with obstetric and/or thrombotic APS and who do not require HCQ for other indications, the use of HCQ during pregnancy is suggested. |
| Women with SLE | **3.5.a:** in women with SLE who are considering pregnancy (or already pregnant):<br>If already being treated with HCQ, it is recommended to continue taking it during pregnancy. |
| | **3.5.b:** in women with SLE who are considering pregnancy (or already pregnant):<br>If not being treated with HCQ, it is suggested to start taking it, unless there are contraindications. |
| | **3.5.c:** in women with SLE who are pregnant, the use of LDA is recommended. |
| Women with SLE in special situations | **3.6.a:** in pregnant women with scleroderma renal crisis, treatment with an ACE inhibitor or an angiotensin receptor blocker is recommended. |
| Preservation of fertility in case of treatment with cyclophosphamide in patients with RD | **3.7.a:** in women of childbearing age with RD treated with cyclophosphamide, it is suggested to start monthly co-therapy with GnRH agonists. |
| | **3.7.b:** in males with RD undergoing cyclophosphamide therapy who are not immediately planning to have a child, it is suggested to avoid co-therapy with testosterone. |

RD, rheumatic diseases; HCQ, hydroxychloroquine; APS, antiphospholipid syndrome; LDA, low-dose acetylsalicylic acid.

**Supplementary Table 5. Recommendations on paternal drug exposure in male patients with rheumatic diseases.**

| Topic and target population | Recommendation |
|---|---|
| Male patients with RD who are planning to have a child within three months. | **4.1.a:** it is recommended to discontinue cyclophosphamide. |
| | **4.1.b:** it is suggested to discontinue talidomide. |
| | **4.1.c:** it is recommended to continue HCQ. |
| | **4.1.d:** it is recommended to continue azathioprine/ 6-mercaptopurine. |
| | **4.1.e:** it is recommended to continue infliximab, etanercept, adalimumab, golimumab, certolizumab. |
| | **4.1.f:** it is recommended to continue colchicine. |
| | **4.1.g:** it is suggested to continue leflunomide |
| | **4.1.h:** it is suggested to continue mycophenolate mofetil/mycophenolic acid. |
| | **4.1.i:** it is suggested to continue NSAIDs or COX-2 inhibitors. |
| | **4.1.l:** it is suggested to continue methotrexate. |
| | **4.1.m:** it is suggested to continue sulfasalazine. |
| | **4.1.n**: it is recommended to continue cyclosporine. |
| | **4.1.o:** it is recommended to continue tacrolimus. |
| | **4.1.p:** it is suggested to continue anakinra. |
| | **4.1.q:** it is suggested to continue rituximab. |
| | **4.1.r:** it is suggested to continue abatacept. |
| | **4.1.s:** it is suggested to continue apremilast. |
| | **4.1.t:** it is suggested to continue belimumab. |
| | **4.1.u:** it is suggested to continue secukinumab. |
| | **4.1.v:** it is suggested to continue tocilizumab. |
| | **4.1.x:** it is suggested to continue ustekinumab. |
| | **4.1.y:** it is suggested to continue JAK-inhibitors. |

RD, rheumatic diseases; NSAIDs, nonsteroidal anti-inflammatory drugs; COX-2, cyclooxygenase-2; HCQ, hydroxychloroquine.

**Supplementary Table 6a. Safety of conventional drugs for pregnant women with rheumatic diseases or those planning a pregnancy (recommendations 4.2).**

| Topic and target population | Recommendation |
|---|---|
| Pregnant women or women planning a pregnancy with RD | **4.2.a:** in case of planning a pregnancy, it is suggested to discuss the possibility that NSAIDs may interfere with conception. |
| | **4.2.b:** in case of pregnancy, it is recommended to avoid NSAIDs in the third trimester. |
| | **4.2.c:** in case of pregnancy, non-selective NSAIDs are suggested (compared to specific COX-2 inhibitors) as they are compatible with pregnancy in the first two trimesters. |
| | **4.2.d**: it is recommended to discontinue methotrexate at least 1-3 months before attempting conception. |
| | **4.2.e:** it is recommended to discontinue mycophenolate mofetil/mycophenolic acid at least 6 weeks before attempting to conceive. |
| | **4.2.f:** it is recommended to discontinue thalidomide before attempting conception. |
| | **4.2.g:** it is recommended to discontinue cyclophosphamide at least 3 months before attempting conception. |
| | **4.2.h:** in case of maternal disease threatening life or organs in which there are no alternative therapies, it is recommended to consider the use of cyclophosphamide in the second or third trimester. |
| | **4.2.i:** if pregnancy occurs during the use of leflunomide, it is recommended to discontinue leflunomide therapy and initiate a washout with cholestyramine. |
| | **4.2.l:** if leflunomide has been discontinued for less than 24 months, it is recommended to start a washout with cholestyramine before attempting conception. |
| | **4.2.m:** it is recommended to continue HCQ as it is compatible with pregnancy. |
| | **4.2.n:** it is recommended to continue sulfasalazine as it is compatible with pregnancy. |
| | **4.2.o:** it is recommended to continue azathioprine/6-mercaptopurine as it is compatible with pregnancy. |
| | **4.2.p:** it is recommended to continue colchicine as it is compatible with pregnancy. |
| | **4.2.q:** it is suggested to continue cyclosporine as it is compatible with pregnancy. |
| | **4.2.r:** it is suggested to continue tacrolimus as it is compatible with pregnancy. |

RD, rheumatic diseases; NSAIDs, nonsteroidal anti-inflammatory drugs; COX-2, cyclooxygenase-2; HCQ, hydroxychloroquine.

**Supplementary Table 6b. The safety of biological drugs for pregnant women or women planning a pregnancy with rheumatic diseases (recommendations 4.3).**

| Topic and target population | Recommendation |
|---|---|
| Pregnant women or women planning a pregnancy with RD | **4.3.a:** it is recommended to continue therapy with certolizumab before and during pregnancy. |
| | **4.3.b:** it is suggested to continue therapy with anti-TNFα (infliximab, etanercept, adalimumab, golimumab) in the first and second trimester. |
| | **4.3.c:** it is suggested to continue rituximab during conception. |
| | **4.3.d:** the use of rituximab during pregnancy in the context of severe, life- or organ-threatening maternal disease is suggested. |
| | **Non-anti-TNFα biologic agents: including anakinra, belimumab, abatacept, secukinumab, and ustekinumab.** |
| | **4.3.e.1:** it is suggested to continue the therapy during conception. |
| | **4.3.e.2:** it is suggested to discontinue therapy at positive pregnancy test. |
| | **Small-molecule-targeted Jak inhibitors e apremilast** |
| | **4.3.f.1:** it is suggested to discontinue JAK inhibitors at least 2 weeks before attempting conception. |
| | **4.3.f.2:** it is suggested to discontinue apremilast before attempting conception. |

RD, rheumatic diseases; TNF, tumor necrosis factor; JAK, Janus kinase.

**Supplementary Table 6c. The use of non-fluorinated glucocorticoids during pregnancy and childbirth in women with rheumatic diseases (recommendations 4.4).**

| Topic and target population | Recommendation |
|---|---|
| Women on chronic low-dose glucocorticoid therapy during pregnancy | **4.4.a:** it is suggested to continue a chronic low-dose (<10 mg/day prednisone or non-fluorinated equivalent) during pregnancy, if clinically indicated. |
| | **4.4.b:** it is recommended to reduce high doses of non-fluorinated glucorticoids to <20 mg/day prednisone by adding a pregnancy-compatible immunosuppressive agent, if necessary. |

**Supplementary Table 6d. The use of non-fluorinated glucocorticoids in women on chronic therapy with low doses of glucocorticoids during delivery (reccomandations 4.5).**

| Topic and target population | Recommendation |
|---|---|
| Women on chronic therapy with low doses of glucocorticoids during delivery | **4.5.a:** it is suggested to evaluate whether to treat with stress-dose of glucocorticoids at the time of vaginal delivery. |
| | **4.5.b:** treatment with stress-dose of glucocorticoids at the time of caesarean delivery is suggested. |

**Supplementary Table 7a. the use of conventional drugs during breastfeeding in women with rheumatic diseases (recommendations 4.6).**

| Topic and target population | Recommendation |
|---|---|
| Breastfeeding women with RD | **4.6.a:** during breastfeeding, the use of NSAIDs is suggested, if necessary, as they are compatible. |
| | **4.6.b:** during breastfeeding, the use of selective COX-2 drugs is suggested if necessary. |
| | **4.6.c:** during breastfeeding, the use of HCQ is recommended, if necessary, as it is compatible. |
| | **4.6.d:** during breastfeeding, the use of sulfasalazine is suggested, if necessary. |
| | **4.6.e:** during breastfeeding, the use of colchicine is suggested, if necessary. |

RD, rheumatic diseases; NSAIDs, nonsteroidal anti-inflammatory drugs; COX-2, cyclooxygenase-2; HCQ, hydroxychloroquine.

**Supplementary Table 7b. The use of immunosuppressive drugs during breastfeeding in women with rheumatic diseases (recommendations 4.7).**

| Topic and target population | Recommendation |
|---|---|
| Breastfeeding women with RD | **4.7.a:** it is recommended not to use leflunomide in women who are breastfeeding. |
| | **4.7.b:** it is recommended not to use mycophenolate mofetil/mycophenolic acid in women who are breastfeeding. |
| | **4.7.c:** it is recommended not to use cyclophosphamide during breastfeeding. |
| | **4.7.d:** it is recommended not to use thalidomide in women who are breastfeeding. |
| | **4.7.e:** it is suggested not to use methotrexate during breastfeeding. |
| | **4.7.f:** during breastfeeding, the use of azathioprine and 6-mercaptopurine is suggested, if necessary. |
| | **4.7.g:** during breastfeeding, the use of ciclosporin is suggested, if necessary. |
| | **4.7.h:** during breastfeeding, the use of tacrolimus is suggested, if necessary. |

RD, rheumatic diseases.

**Supplementary Table 7c. The use of biological drugs during breastfeeding in women with rheumatic diseases (recommendations 4.8).**

| Topic and target population | Recommendation |
|---|---|
| Breastfeeding women with RD | **4.8.a:** during breastfeeding, the use of anti-TNFα is recommended as a class: infliximab, etanercept, adalimumab, golimumab, certalizumab, if necessary, as they are compatible. |
| | **4.8.b:** during breastfeeding, the use of rituximab is recommended, if necessary, as it is compatible. |
| | **4.8.c:** during breastfeeding, the use of belimumab is recommended, if necessary. |
| | **4.8.d:** during breastfeeding, the use of tocilizumab is recommended, if necessary. |
| | **4.8.e:** the use of anakinra in women who are breastfeeding is suggested. |
| | **4.8.f:** the use of abatacept in women who are breastfeeding is suggested. |
| | **4.8.g:** the use of secukinumab is suggested in women who are breastfeeding. |
| | **4.8.h:** the use of ustekinumab is suggested in women who are breastfeeding. |
| | **4.8.i:** during breastfeeding, it is suggested not to use JAK inhibitors and apremilast. |

RD, rheumatic diseases; TNF, tumor necrosis factor; JAK, Janus kinase.

**Supplementary Table 7d. The use of glucocorticoid drugs during breastfeeding in women with rheumatic diseases.**

| Topic and target population | Recommendation |
|---|---|
| Breastfeeding women with RD | **4.9.a:** the use of prednisone <20mg/day (or non-fluorinated equivalent) during breastfeeding is recommended, if necessary, as compatible. |
| | **4.9.b:** it is recommended that women using prednisone >20mg daily (or non-fluorinated equivalent) delay breastfeeding or discard breast milk for the next four hours. |

RD, rheumatic diseases.