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CRITERIOS PARA EL DIAGNOSTICO DE PERDIDA REPRODUCTIVA EN EL PRIMER TRIMESTRE

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Aborto espontáneo

Protocolo actualizado en julio de 2010
(Sustituye al protocolo sobre Hemorragias del I trimestre)

Los signos ecográficos que permiten de forma inequívoca establecer el diagnóstico de aborto diferido son:

- Ausencia de actividad cardiaca en un embrión con longitud céfalo-caudal (LCC) >5 mm (grado de recomendación B)[13].
- Ausencia de actividad cardiaca en un embrión con LCC >3,5 mm inequívocamente demostrada por un evaluador experimentado en condiciones óptimas para la visualización del embrión (grado de recomendación B)[14] o,
- Saco gestacional con un diámetro medio ≥20 mm sin evidencia de polo embrionario ni saco vitelino en su interior (grado de recomendación B)[15].

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Ultrasound Obstet Gynecol 2011; 38: 497–502
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Limitations of current definitions of miscarriage using mean gestational sac diameter and crown–rump length measurements: a multicenter observational study

Y. ABDALLAH*, A. DAEMEN†, E. KIRK*, A. PEXSTERS†, O. NAJI*, C. STALDER‡, D. GOULD§, S. AHMED§, S. GUHA¶, S. SYED§, C. BOTTOMLEY¶, D. TIMMERMAN† and T. BOURNE*†

Table 2 Performance in all centers of different cut-off values of mean gestational sac diameter (MSD) in absence of both yolk sac and embryo for prediction of non-viable pregnancy at 11–14 weeks ($n = 462$)

MSD (mm)	*Sensitivity (% (n))*	*Specificity (% (n))*	*95% CI for specificity*	*PPV*	*NPV*
8	49.1 (137/279)	63.9 (117/183)	56.8–70.5	0.67	0.45
10	35.8 (100/279)	80.3 (147/183)	74.0–85.4	0.74	0.45
12	26.5 (74/279)	88.0 (161/183)	82.5–91.9	0.77	0.44
14	17.6 (49/279)	92.9 (170/183)	88.2–95.8	0.79	0.43
16	13.6 (38/279)	95.6 (175/183)	91.6–97.8	0.83	0.42
18	6.5 (18/279)	98.9 (181/183)	96.1–99.7	0.90	0.41
20	2.9 (8/279)	99.5 (182/183)	97.0–99.9	0.89	0.40
21	2.9 (8/279)	100 (183/183)	97.9–100	1	0.40

NPV, negative predictive value; PPV, positive predictive value.

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Table 4 Performance in all centers of different cut-off values of crown–rump length (CRL) in absence of fetal heart activity for prediction of non-viable pregnancy at 11–14 weeks ($n = 179$)

CRL (mm)	*Sensitivity (% (n))*	*Specificity (% (n))*	*95% CI for specificity*	*PPV*	*NPV*
3.0	71.6 (111/155)	75.0 (18/24)	55.1–88.0	0.95	0.29
3.2	67.1 (104/155)	83.3 (20/24)	64.2–93.3	0.96	0.28
3.4	63.9 (99/155)	87.5 (21/24)	69.0–95.7	0.97	0.27
3.6	61.9 (96/155)	87.5 (21/24)	69.0–95.7	0.97	0.26
3.8	56.8 (88/155)	87.5 (21/24)	69.0–95.7	0.97	0.24
4.0	49.7 (77/155)	91.7 (22/24)	74.2–97.7	0.97	0.22
4.2	41.9 (65/155)	91.7 (22/24)	74.2–97.7	0.97	0.20
4.4	37.4 (58/155)	91.7 (22/24)	74.2–97.7	0.97	0.18
4.6	34.2 (53/155)	91.7 (22/24)	74.2–97.7	0.96	0.18
4.8	29.7 (46/155)	91.7 (22/24)	74.2–97.7	0.96	0.17
5.0	22.6 (35/155)	91.7 (22/24)	74.2–97.7	0.95	0.15
5.2	20.0 (31/155)	91.7 (22/24)	74.2–97.7	0.94	0.15
5.3	16.8 (26/155)	100 (24/24)	86.2–100	1	0.16

NPV, negative predictive value; PPV, positive predictive value.

Variabilidad
Inter-intra observador
del 18,78%

- MSD 20 mm (16,8-24,5)
- CRL 6 mm (5,4-6,7)

INCREMENTAR LOS NIVELES DE CORTE PARA EVITAR ERRORES

A study in this issue of the Journal, reporting the inter- and intraobserver variability of MSD and CRL measurements reveals, for MSD, the limits of agreement to be ±18.78%[9]. So, an MSD measurement of 20 mm by one examiner may translate to a measurement of anywhere between 16.8 and 24.5 mm for a second examiner, while a CRL measurement of 6 mm translates to a range for a second examiner of between 5.4 mm and 6.7 mm. This suggests that safe cut-off values to define miscarriage may have to be significantly increased to exclude any errors. These data suggest that decisions to intervene and allow the potential termination of a viable pregnancy are being taken based on inappropriate guidance.

When is a pregnancy nonviable and what criteria should be used to define miscarriage?

TABLE 2

MSD measurement range by the second observer for an MSD measured by the first observer.

MSD of first observer (mm)	95% PI for MSD of second observer (mm)
10	8.5–12.6
15	12.7–18.6
16	13.5–19.8
17	14.3–21.0
18	15.1–22.2
19	16.0–23.4
20	16.8–24.5
21	17.6–25.7
22	18.4–26.9
23	19.2–28.0
24	20.0–29.2
25	20.9–30.4
30	24.9–36.1
40	32.5–47.6

Note: Taken from: Pexsters A, et al. (13), with permission. MSD = mean sac diameter; PI = prediction interval.

Bourne. When can we say an early pregnancy is nonviable? Fertil Steril 2012.

TABLE 1

CRL measurement range by the second observer for a CRL measured by the first observer.

CRL1 of first observer (mm)	95% PI for CRL1 of second observer (mm)
5	4.5–5.6
6	5.4–6.7
7	6.3–7.9
10	8.9–11.2
20	17.9–22.4
30	26.7–33.5

Note: Taken from: Pexsters A, et al. (13), with permission. CRL1 = crown-rump length, first measurement; PI = prediction interval.

Bourne. When can we say an early pregnancy is nonviable? Fertil Steril 2012.

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Conclusions *These data show that some current definitions used to diagnose miscarriage are potentially unsafe. Current national guidelines should be reviewed to avoid inadvertent termination of wanted pregnancies. An MSD cut-off of > 25 mm and a CRL cut-off of > 7 mm could be introduced to minimize the risk of a false-positive diagnosis of miscarriage.*

MSD > 25 mm
CRL > 7 mm

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Accuracy of first-trimester ultrasound in the diagnosis of early embryonic demise: a systematic review

Y. JEVE*, R. RANA†, A. BHIDE† and S. THANGARATINAM‡

Results *Eight primary articles with four test categories (18 2 × 2 tables), involving 872 women, evaluated the accuracy of ultrasound in diagnosing early embryonic demise. The lower limit of the 95% CI for specificity was > 0.95 in only two tests. These were an empty gestational sac with mean diameter of ≥ 25 mm and absent yolk sac with a mean gestational sac diameter of ≥ 20 mm (specificity, 1.00; 95% CI, 0.96–1.00 for both).*

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In many developed countries, women can now be managed expectantly without the need for medical treatment or surgery. Waiting 7–10 days in order to repeat a scan is highly unlikely to lead to physical harm. The anxiety associated with being uncertain about the status of a pregnancy is very significant, but should be balanced against the possibility of inadvertent termination which is surely the worst possible outcome for any woman.

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repeat scan. In a further paper in this Journal[17], we have shown that it is possible for there to be no growth in MSD over at least 10 days and the pregnancy still to be viable.

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Ectopic pregnancy and miscarriage

Diagnosis and initial management in early pregnancy of ectopic pregnancy and miscarriage

Issued: December 2012

NICE clinical guideline 154
guidance.nice.org.uk/cg154

1.4 Diagnosis of viable intrauterine pregnancy and of ectopic pregnancy

Using ultrasound for diagnosis

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1.4.7 If the crown–rump length is 7.0 mm or more with a transvaginal ultrasound scan and there is no visible heartbeat:

- seek a second opinion on the viability of the pregnancy **and/or**
- perform a second scan a minimum of 7 days after the first before making a diagnosis.

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1.4.10 If the mean gestational sac diameter is 25.0 mm or more using a transvaginal ultrasound scan and there is no visible fetal pole:

- seek a second opinion on the viability of the pregnancy **and/or**

- perform a second scan a minimum of 7 days after the first before making a diagnosis.

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Expectant management

- Use expectant management for 7–14 days as the first-line management strategy for women with a confirmed diagnosis of miscarriage. Explore management options other than expectant management if:

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Setting standards to improve women's health

Green-top Guideline No. 25
October 2006

THE MANAGEMENT OF EARLY PREGNANCY LOSS

- Pregnancy of 'uncertain viability': Intrauterine sac (<20 mm mean diameter) with) no obvious yolk sac or fetus

  or

  Fetal echo <6 mm crown-rump length with no obvious fetal heart activity. In order to confirm or refute viability, a repeat scan at a minimal interval of 1 week is necessary.[14]

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Addendum to GTG No 25 (Oct 2006): The Management of Early Pregnancy Loss

Recent research suggests that given inter-observer variability in ultrasound measurements and the greater variation in early embryonic growth than has hitherto been assumed, a more conservative approach to the diagnosis of early pregnancy loss is warranted.

Having carefully considered these papers, we recommend adoption of the following interim guidance **with immediate effect**:

1. Ultrasound diagnosis of miscarriage should only be considered with a mean gestation sac diameter >/= 25mm (with no obvious yolk sac), or with a fetal pole with crown rump length >/=7mm (the latter without evidence of fetal heart activity)

2. A transvaginal ultrasound scan should be performed in all cases

3. Where there is any doubt about the diagnosis and/or a woman requests a repeat scan, this should be performed at an interval of at least one week from the initial scan before medical or surgical measures are undertaken for uterine evacuation. No growth in gestation sac size or CRL is strongly suggestive of a non-viable pregnancy in the absence of embryonic structures.

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Addendum to GTG No 25 (Oct 2006): The Management of Early Pregnancy Loss

Recent research suggests that given inter-observer variability in ultrasound measurements and the greater variation in early embryonic growth than has hitherto been assumed, a more conservative approach to the diagnosis of early pregnancy loss is warranted.

These revised values for 'mean gestation sac diameter' and 'crown rump length' do not imply that previously used values were wrong, nor that diagnosis of miscarriage in the past has been unsafe, This interim guidance suggests a more cautious approach is warranted, pending more definitive data becoming available. It extends the criteria included in the RCOG Green Top Guideline No 25, which recommended a conservative approach with mean gestation sac diameter <20mm or fetal CRL <6mm.

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La sospecha de embarazo ectópico es alta cuando por ecografía transvaginal se objetiva un útero vacío y los niveles de β-hCG sérica son >1800 mUI/mL. **(B)**

Métodos de evacuación uterina

La evacuación quirúrgica del útero debe realizarse usando el legrado por aspiración (grado de recomendación A)[22] ya que se asocia a menor pérdida de sangre, menor dolor y con una duración más corta del procedimiento[24]. Sin embargo, debe evitarse en gestaciones menores de 7 semanas de gestación por las posibilidades de fracaso (grado de recomendación B)[21].

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Green-top Guideline No. 25
October 2006

Si Anti-D

- **Ectópico**
- **Aborto por encima de 12 sem.**
- **A de aborto (> 12 s)**
- **Aborto con tto medico**

No Anti-D

- **Aborto espontaneo por debajo de 12 sem. (sin tto)**
- **A de aborto (< 12 s) sin clínica**

Anti-D immunoglobulin should only be given for threatened miscarriage under 12 weeks gestation when bleeding is heavy or associated with pain. It is not required for cases of complete miscarriage under 12 weeks of gestation when there has been no formal intervention to evacuate the uterus.

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1.7 Anti-D rhesus prophylaxis

1.7.1 Offer anti-D rhesus prophylaxis at a dose of 250 IU (50 micrograms) to all rhesus negative women who have a surgical procedure to manage an ectopic pregnancy or a miscarriage.

1.7.2 Do not offer anti-D rhesus prophylaxis to women who:

- receive solely medical management for an ectopic pregnancy or miscarriage **or**
- have a threatened miscarriage **or**
- have a complete miscarriage **or**
- have a pregnancy of unknown location.

1.7.3 Do not use a Kleihauer test for quantifying feto–maternal haemorrhage.

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U.S. Department of Health & Human Services www.hhs.gov

AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care www.ahrq.gov

National Guideline Clearinghouse

Guideline Summary NGC-8803

Guideline Title

The use of anti-D immunoglobulin for rhesus D prophylaxis.

Bibliographic Source(s)

Royal College of Obstetricians and Gynaecologists (RCOG). The use of anti-D immunoglobulin for rhesus D prophylaxis. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2011 Mar. 14 p. (Green-top guideline; no. 22). [37 references]

Administration

How Should Anti-D Ig Be Administered?

D - For successful immunoprophylaxis, anti-D Ig should be given as soon as possible after the potentially sensitising event but always within 72 hours. If it is not given before 72 hours, every effort should still be made to administer the anti-D Ig, as a dose given within 10 days may provide some protection.

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Guideline Summary NGC

Guideline Title

The use of anti-D immunoglob

Bibliographic Source(s)

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London (UK): Royal College of
[37 references]

s D prophylaxis.
uideline; no. 22).

Prophylaxis Following Miscarria

When Is Anti-D Ig Prophylaxis

nation of Pregnancy?

No Anti-D

- **Aborto espontaneo por debajo de 12 sem. (sin tto)**
- **A de aborto (< 12 s) sin clínica**

Miscarriage

D - Anti-D Ig should be given to a
mplete or incomplete miscarriage at or after 12^{+0} weeks

D - Anti-D Ig is not required for spontaneous miscarriage before 12^{+0} weeks of gestation, provided there is no instrumentation of the uterus.

D - Anti-D Ig should be given to non-sensitised RhD-negative women undergoing surgical evacuation of the uterus, regardless of gestation.

D - Anti-D Ig should be considered for non-sensitised RhD-negative women undergoing medical evacuation of the uterus, regardless of gestation.

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Si Anti-D

- **Ectópico**
- **A de aborto (> 12 s).**
- **A Aborto con clínica, independiente de edad gestacional**

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National Guideline Clearinghouse

Guideline Summary NG

Guideline Title

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Bibliographic Source(s)

Royal College of Obstetricians
London (UK): Royal College of
[37 references]

bulin for rhesus D prophylaxis.
. (Green-top guideline; no. 22).

Ectopic Pregnancy

D - Anti-D Ig should be given to
ctopic pregnancy, regardless of management.

Threatened Miscarriage

D - Anti-D Ig should be given to all non-sensitised RhD-negative women with a threatened miscarriage after 12^{+0} weeks of gestation. In women in whom bleeding continues intermittently after 12^{+0} weeks of gestation, anti-D Ig should be given at 6-weekly intervals.

D - Anti-D Ig should be considered in non-sensitised RhD-negative women if there is heavy or repeated bleeding or associated abdominal pain as gestation approaches 12^{+0} weeks.

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Segunda edición

Organización Mundial de la Salud

No obstante, en los embarazos con una edad gestacional de 9 semanas (63 días) como máximo, el riesgo teórico de sensibilización Rh con un aborto médico es muy bajo (*17*). En consecuencia, la determinación del factor Rh y la administración de profilaxis anti-D no se consideran prerrequisitos para un aborto médico temprano (*12*). Si se dispone de inmunoglobulina Rh, se recomienda su administración a las mujeres con factor Rh negativo sometidas a un aborto médico en el mismo momento en que se administre prostaglandina (*18*). En el caso de las mujeres que utilicen misoprostol en su hogar, la inmunoglobulina R puede administrarse a la vez que la mifepristona.

Aborto espontáneo

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Esta profilaxis consiste en la administración IM de 300 µg de inmunoglobulina anti-D, lo antes posible después de la intervención y siempre antes de las primeras 72 horas. Pese a todo, si no se puede realizar en este periodo por circunstancias excepcionales, parece que hasta 10 días después del evento la profilaxis puede producir algún beneficio (grado de recomendación B)[36]. En gestaciones de ≤12 semanas, una dosis de 150 µgr sería suficiente[37].

Todas las gestantes Rh negativas que no estén sensibilizadas y que hayan tenido un aborto espontáneo, completo o incompleto, por métodos médicos o quirúrgicos, deben recibir profilaxis de la isoinmunización Rh. **(B)**

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Estudio histológico

El ginecólogo debe examinar el tejido extraído para confirmar que son restos abortivos, que su cantidad es adecuada y para descartar la presencia de tejido extraño como grasa[28]. No se recomienda el estudio histológico rutinario de los restos abortivos (grado de recomendación B)[21], aunque sí estaría indicado cuando haya que confirmar la gestación y excluir el embarazo ectópico (poco material) o que se trate de una posible enfermedad trofoblástica gestacional (tejido con vesículas) (grado de recomendación C)[22].

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Estudio histológico

No se recomienda el estudio histológico rutinario de los restos abortivos **(B)**, salvo cuando haya que confirmar la gestación y excluir el embarazo ectópico o se trate de una posible enfermedad trofoblástica gestacional. **(C)**

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ABORTO SIN RIESGOS

Gu a t cnica y de pol ticas para Sistemas de Salud

ORGANIZACIÓN MUNDIAL DE LA SALUD
GINEBRA 2003

2.3.5 Evaluación de los tejidos posterior a un aborto quirúrgico

El análisis rutinario del producto de la concepción por un laboratorio de patología no es esencial.

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CONSEJERÍA DE SALUD
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NORTE DE ALMERÍA

UGC Ginecología

Royal College of Obstetricians and Gynaecologists

Setting standards to improve women's health

Green-top Guideline No. 25
October 2006

THE MANAGEMENT OF EARLY PREGNANCY LOSS

Tissue obtained at the time of miscarriage should be examined histologically to confirm pregnancy and to exclude ectopic pregnancy or unsuspected gestational trophoblastic disease.

C

Heath *et al.* suggested that there is no obvious benefit in routine histological investigation of tissue obtained from cases of pregnancy termination and miscarriage.[66] However, within a subgroup of 468 undergoing surgical evacuation for miscarriage, there were two cases of ectopic pregnancy diagnosed 25 and 28 days post-evacuation (an incidence of 0.42%). Neither was suspected on scan but histology had reported 'decidua only'. In view of the maternal risks associated with ectopic pregnancy and molar pregnancy, it is recommended that practitioners should always consider sending tissue obtained at the time of uterine evacuation (medical or surgical) for histological examination. This may confirm the diagnosis of miscarriage and can help to exclude ectopic pregnancy or gestational trophoblastic disease.[6]

Evidence level IV

Diapositiva 29

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British Journal of Obstetrics and Gynaecology
June 2000, Vol 107, pp. 727–730

Should tissue from pregnancy termination and uterine evacuation routinely be examined histologically?

1576 legrados -93% se confirma gestación

- 6% decidua (87 casos), hubo dos ectopicos no sospechados por la eco (1,2 por mil).

- 2 molas sospechadas (2/8) que se confirmaron

- 2 abortos confirmados que continuaron la gestación

- Diagnosticados por la clínica a las 25 y 28 días.

British Journal of Obstetrics and Gynaecology
June 2000, Vol 107, pp. 727–730

Should tissue from pregnancy termination and uterine evacuation routinely be examined histologically?

Conclusion There did not appear to be any obvious benefit from routine histological examination of tissue removed at termination of pregnancy or emergency uterine evacuation. The histological result was sometimes not consistent with the pre-operative diagnosis and may result in unnecessary further investigation and treatment unless due consideration is given to the clinical presentation.

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November 2011

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Bringing to life the best in women's health care

The Care of Women Requesting Induced Abortion

Evidence-based Clinical Guideline Number 7

7.3 Histopathology

RECOMMENDATION 7.28

C Routine histopathological examination of tissue obtained at abortion procedures is not recommended.

Evidence supporting recommendation 7.28

Three prospective cohort studies have examined the usefulness of routine histopathological examination of tissue obtained at abortion.[381–383] Two of them concluded that there was no obvious benefit from routine histological examination. The third study involved review of histological findings from 1000 consecutive induced abortions at 7–13 weeks of gestation.[381–383] Pathological findings were reported in 5.6% of cases, including one diagnosis of fetal polycystic kidney disease. The authors reported that this information enabled the woman to undergo prenatal diagnosis in future pregnancies and argued a case for routine histological examination of abortion material. However, none of the pathologies reported influenced the immediate care of the woman.

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The Royal College of Pathologists' guidance on histopathological examination of tissue obtained at abortion finds it to be of limited or no clinical value and advises that for 'social termination of pregnancy', specimens should not be sent to the laboratory if fetal parts are visible.[384] With early surgical abortion, fetal parts may not be visible. Therefore, histological examination would be indicated when a gestational sac is not seen in the aspirate (see recommendation 7.3).

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Gestational trophoblastic neoplasia (GTN)

RECOMMENDATION 7.29

C Routine screening of women for GTN at the time of abortion is not recommended; providers should be aware of the signs and symptoms and, where appropriate, facilitate referral into a GTN monitoring programme.

RECOMENDACIONES

1.Diagnostico de gestación no evolutiva: DMS>25 mm sin estructuras embrionarias. CRL>7 mm sin LC.
2.No hacer el diagnostico en una sola visita, revisión en 7-10 días.
3.Administración de anti-D, tan pronto como sea posible, después del evento, siempre dentro de las primeras 72 horas, puede ser efectivo dentro de los 10 siguientes días.
4.No poner anti-d: abortos espontáneos por debajo de las 12 semanas.
5.Poner anti-d: ectópico, siempre que se realice un tto medico o quirúrgico del aborto. A de aborto= o > 12 s.
6.No estudio histológico del aborto, excepto: sospecha de enf. Trofoblastica.

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Gracias por la atención